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Development and application of novel methods to inform surgical study design

a case study in parastomal hernia prevention

Development and application of novel methods to inform surgical study design: a case study in parastomal hernia prevention

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Abstract

Surgical interventions are complex and consequently designing studies to evaluate their outcomes is challenging. A key obstacle is the variability within surgical interventions. Variations in surgical procedure and peri-operative care can act independently or collectively to influence outcomes. Understanding these variations and their ability to affect outcomes is fundamental to the success of any surgical research and deciding what data to collect to adequately capture variability is a difficult question.

This Masters addresses the challenge of collecting data on surgical interventions through applying and developing novel methods to develop case report forms. This research was performed as feasibility work for the CIPHER study, a large cohort study investigating risk factors for the development of parastomal hernias. The feasibility work aimed to identify all possible variations in terms of the surgical intervention and peri-operative care, which could be incorporated into a comprehensive data collection tool for use within the main study.

A literature review using snowballing methods, and mixed qualitative research methods including interviews and non-participant observations were employed to identify the 'known' and 'unknown' variations respectively, and ensure all possible variations were understood and explored. The variations formed a long-list of data items for consideration within the CIPHER study. A consensus meeting of experts prioritised this list into a manageable number of 'essential' data items ready to be used in the final case report forms for the cohort study.

The findings of this study demonstrated the lack of consensus among surgeons regarding factors that influence parastomal hernia development, and considerable variations in surgical techniques for stoma formation. This supported the need for the CIPHER study, and justified the value of such detailed feasibility work to be completed. The combination of research methods was successful and provided unique findings that could not have been identified if only one method of data collection had been employed. These methods can be adapted for future research studies involving complex interventions such as surgery.

Author's declaration

I declare that this work was carried out in accordance with the requirements of the University's Regulations and Code of Practice for Research Degree Programmes and has not been submitted for any other academic award. Except where indicated by specific reference in the text, this is all the candidate's own work. Work done in collaboration with, or with the assistance of others, is indicated as such. Any views expressed in the dissertation are those of the author.

Signed .... Date: ....

Declaration

The following individuals assisted with this thesis:

Miss Natalie Blencowe (NB), Academic Clinical Lecturer in General Surgery, University of Bristol, was the joint main supervisor of this thesis and helped with study conception, the design of the literature review and the design of the mixed qualitative methods research. Assisted in the literature review, including determining the index paper and double-coding the articles. Assisted in the mixed qualitative methods research; reviewed the observation guide and topic guide, watched operative videos and transcribed them. Assisted in determining the long-list of data items. Assisted during the consensus meeting, reviewing the short-list and reviewed and made comments on all aspects of the thesis.

Professor Jane Blazeby (JMB), Professor of Surgery, University of Bristol, and Honorary Consultant Surgeon, University Hospitals Bristol NHS Foundation Trust was the joint main supervisor of this thesis and helped with study conception, the design of the literature review and design of the mixed qualitative methods research. Advised the mixed qualitative methods work, reviewed the topic guide and long-list development. Advised and assisted in the consensus meeting and reviewed and made comments on all aspects of the thesis. She provided strategic guidance throughout and she established the liaison between the work and the CIPHER study.

Dr Leila Rooshenas (LR), Lecturer in Qualitative Health Science, University of Bristol, co-supervised this thesis and helped with study conception and design of the qualitative work. She assisted in the literature review by double-coding articles and checking the quality of the coding framework. Advised on the semi-structured interviews and non-participant observations. Advised on the qualitative aspects of the work; listened to the semi-structured interviews, double-coded a proportion of the qualitative interviews and reviewed the topic guides. Assisted in the consensus meeting. Reviewed as well as commented on all aspects of this thesis with special attention to the qualitative aspects.

Mr Neil Smart (NS), Colorectal Surgeon and Associate Professor of Surgery, University of Exeter, CIPHER study Chief Investigator, assisted in the study conception, assisted with recruitment and provided advice on the long-list and chaired the consensus meeting.

Professor Barney Reeves (BR), Professorial Research Fellow in Health Services Research, University of Bristol, attended the consensus meeting and provided additional input into the short-list of data items.

Mr Ian Daniels, Consultant Colorectal Surgeon, Royal Devon and Exeter Hospital; Mr Tom Pinkney, Consultant Colorectal Surgeon, Queens University Hospital Birmingham; Mr Jamshed Shabbir, Consultant Colorectal Surgeon, University Hospitals Bristol NHS Foundation Trust; Miss Joanne Bennett, Colorectal Registrar, North Bristol NHS Trust; Professor Timothy Rockall, Professor of Surgery, Consultant Colorectal Surgeon, Royal Surrey County Hospital, all attended the consensus meeting and provided comments on the long-list of data items.

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Conor Jones (CJ), Medical student, University of Exeter assisted in the digital video data capture at the Royal Devon and Exeter Hospital.

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Glossary of abbreviations

ACPGBI	Association of Coloproctology of Great Britain and Ireland
UHB	University Hospitals Bristol NHS Foundation Trust
CAQDAS	Computer Assisted Qualitative Data Analysis Software
CI	Chief Investigator
CIPHER	UK Cohort Study Investigating the Prevention of parastomal HERnia
CRF	Case Report Forms
CTEU	Bristol Clinical Trials and Evaluation Unit
HCP	Healthcare Professional Participant
ILL	Inter Library Loan
MRC	Medical Research Council
MSc	Master of Science
NHS	National Health Service
NIHR HTA	National Institute for Health Research Health Technology Assessment Programme
PI	Principle Investigator
PSH	Parastomal Hernia
PROM	Patient reported outcome measure
QEH	Queen Elizabeth Hospital
RDE	Royal Devon and Exeter Hospital
SLR	Systematic literature review
UK	United Kingdom

CHAPTER 1. INTRODUCTION

This introductory chapter discusses the background and rationale for performing this research. Firstly, an overview of the challenges to performing surgical research is presented, with a focus on the complexity of surgical interventions. Secondly, it introduces the current thinking on parastomal hernia (PSH) prevention and discusses the research gaps. Finally, it describes how this research will be used to inform the design of the CIPHER study data collection forms.

1.1 Background

1.1.1 Challenges to surgical research

Surgical research is notoriously difficult to conduct because of multiple methodological and practical issues. There are consistently fewer high-quality studies that evaluate surgical interventions compared to pharmacological interventions (2). The main types of studies used to evaluate healthcare interventions are Randomised Controlled Trials (RCTs) and observational studies. RCTs are considered the gold standard method to compare the effectiveness of interventions because participants are subjected to randomisation, where they are allocated to the intervention or the control group. This process allows those interpreting the study to assume that any confounding factors are evenly distributed between the intervention and the control group so that any difference in outcomes can be attributed to the healthcare intervention. Many have criticised the lack of RCTs in surgery (3). Reasons for the lack of surgical RCTs include practical issues such as cost, the level of organisation required, strong patient preferences, lack of surgeon equipoise and difficulty blinding (4-7). When surgical RCTs are performed they are often flawed due to various methodological issues and quality concerns (8, 9). Between 1966 and 2000, only 3.4% of articles published in five leading surgical journals were RCTs (10). As such, most surgical interventions performed in current practice have yet to undergo rigorous RCT investigation.

Currently, observational studies account for the majority of the evidence in surgical literature (11). Cohort studies and case control studies are two commonly used types of observational study. Observational studies do not randomise participants but 'observe' differences in outcomes that occur after treatment decisions have been made to identify risk factors of diseases or healthcare events (12). Observational studies' biggest criticism is that they are subject to selection bias as they fail to control for unexpected confounding influences that may impact outcomes. Subsequently, observational studies are considered to produce lower quality evidence than RCTs as demonstrated by their inferior position in the hierarchy of evidence pyramid (Figure 1).

However, a well-designed observational study can still contribute to the evidence base and can provide results similar to RCTs (13, 14). Observational studies can also be useful for generating hypotheses that can later be tested through RCTs (15, 16). A review by Solomon et al noted that only 40% of questions evaluating a surgical intervention may be answerable by an RCT (4). There are occasions where it may be preferable to employ an observational study design when ethical, financial and recruitment considerations preclude an RCT (12, 15, 17).

There are challenges to evaluating surgical interventions that are common to both RCT and observational designs. Designing high-quality studies in the surgical field requires an appreciation of the factors that make surgical research more complicated to perform than research in the medical field. Unique difficulties that complicate the investigation of surgical interventions include the constant change and evolution of surgical interventions, making it hard to ascertain the right time to do a surgical study; managing the 'surgical learning curve'; defining and selecting outcomes; and importantly, designing studies that deal with the complexity of surgical interventions. Each of these difficulties is discussed below.

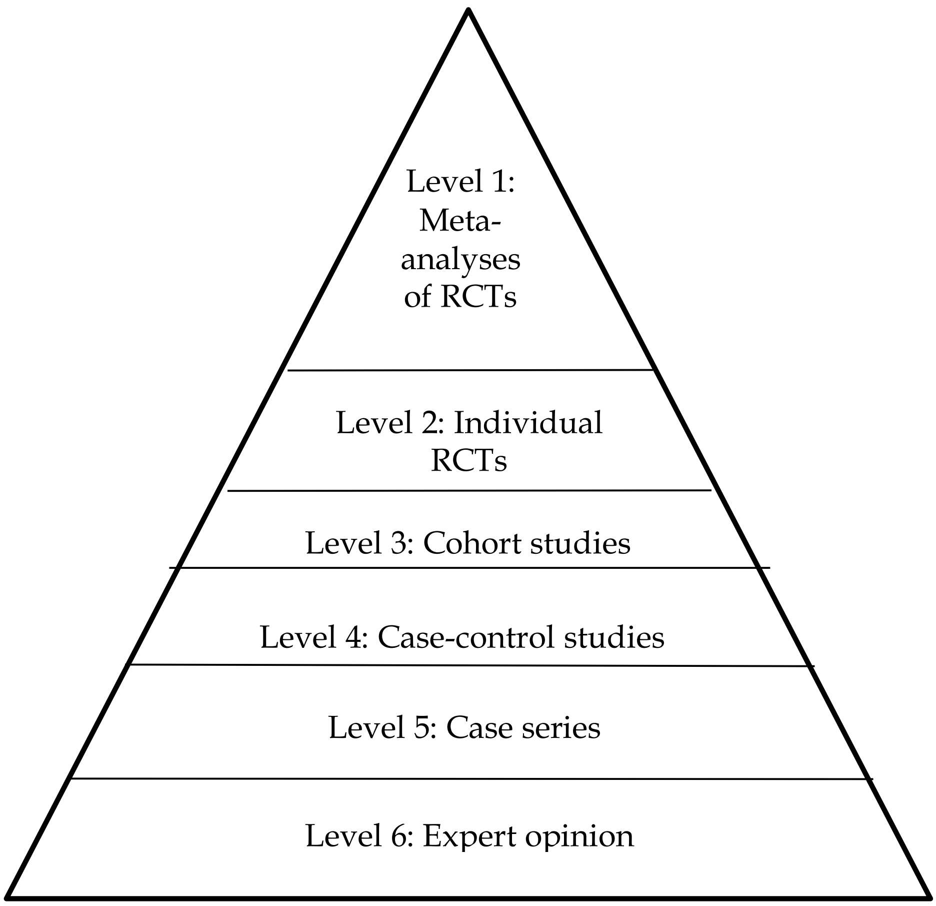

Figure 1: Hierarchy of evidence pyramid (1)

1.1.1.1 Determining the right time to do a surgical study

The optimal time to conduct a surgical study, in relation to an intervention's stage of development, is often uncertain. In 1987, Buxton stated that 'it's always too early until, unfortunately, it's suddenly too late' in relation to conducting randomised evaluations of surgical interventions (18). For example, performing a study too early within the development of a surgical innovation risks it being too experimental and not in a stable form, leading to possible criticisms that the study was limited by "learning effects"(19). There are also problems associated with waiting for an intervention to stabilise because at this point, surgeons may be reluctant to recruit patients if they believe the intervention to be better than standard care, meaning that equipoise is lost and recruitment is not possible.

1.1.1.2 Managing the surgical learning curve

The "surgical learning curve" refers to the phenomenon where surgeons acquire and improve skills, and this impacts on patient outcomes, over time (2). Variability can therefore be expected based on the participating surgeons' previous experiences and training. Some studies have chosen to recruit only experienced surgeons who have completed their training so that the intervention is evaluated in optimal conditions. However, this would affect the generalisability of the study's results, because in real-life practice surgeons of all grades perform or participate in surgical interventions.

An example of the potential impact that the surgical learning curve can have on the interpretation of the study's results comes from the field of general surgery. Morris et al presented a retrospective analysis that aimed to assess the variation in risk-adjusted 30-day postoperative mortality for patients with colorectal cancer across all major colorectal cancer services in the United Kingdom (UK) (20). The results showed a wide disparity in 30-day mortality rates and for clinical anastomotic leak (a measure of technical success) across the UK. Critics of the article recommended the recognition of surgeon-related variance as an important confounder and made a plea that the authors of the article return to their data and stratify the results by level of experience that the operating surgeon had, i.e. consultant, senior registrar and registrar (21). Documenting the experience of the surgeon may offer valuable insights into how surgeon experience affects surgical outcomes. However, reporting the results of only the most experienced surgeons to assess the interventions true effectiveness by investigating it in the most ideal conditions reduces the generalisability of the study.

1.1.1.3 Outcome selection and definition

It may be difficult to define outcomes relating to surgical interventions. This was highlighted in a systematic review investigating the reporting of adverse surgical events which identified 41 different definitions of a wound infection and 13 grading scales for the assessment of that outcome (22). A lack of standardised definitions and methods for outcome assessment can make it difficult to interpret and compare results across studies. A further challenge to selecting outcomes for some types of surgical research is ensuring that they are patient centred. Surgeons traditionally focus on clinical parameters, such as mortality and length of hospital stay. In recent years there has been a shift of interest towards additional outcomes that are important to patients, such as long-term quality of life with the use of patient reported outcome measures (PROMs) to be used in RCTs. These outcomes come directly from the patient and are usually collected in the form of a questionnaire and their use is recommended by funding and regulatory agencies (23). However, PROMs are also subject to heterogeneity. For example, a systematic review of outcomes in colorectal cancer surgery identified 58 different PROMs used to assess the patient experience of colorectal surgery (24). This makes synthesis of outcome data difficult across multiple studies.

1.1.1.4 The complexity of surgical interventions

A major challenge facing surgical research is that surgery is considered to be a complex healthcare intervention (2, 19). Complex healthcare interventions can be defined as those containing multiple components, which act independently or interdependently to influence outcomes (25). This complexity has consequences for study design and conduct (discussed in further detail in Section 1.1.2.).

1.1.2 The challenges of surgery as a complex intervention

Recently, the research community has recognised surgery as a complex intervention and acknowledged that this may be a barrier to the design and conduct of high quality research (26, 27). Each surgical intervention is comprised of multiple technical components that make up the stages of the operation, all of which may vary in their delivery. In addition, there can be non-technical variations including other factors aligned with pre-, peri- and post-operative care, the context in which a surgical intervention is delivered, as well as the expertise with which it is delivered by the surgeon(s) and their team.

Pre-, peri- and post-operative care can include a broad range of interventions such as medications, anaesthesia, intensive care interventions such as central lines, as well as post-operative physiotherapy. Surgical interventions and their associated concomitant interventions may be delivered within a variety of contexts that differ according to factors such as surgeon preference, staffing levels, the availability of equipment, which are related to the overall financial resources available. Other influences include the interaction between surgeon and procedure, including surgical skill and experience (2). All of these factors may influence how an intervention is delivered within a study, as well as its outcomes, and thus have implications for study design. This is because the evaluation of a complex intervention will need to account for this inherent complexity and therefore is likely to be different to that required for 'simple' interventions such as drugs (28).

1.1.2.1 Describing a complex intervention within a study

An important consideration when designing studies evaluating complex interventions is how to define and describe the intervention under investigation (29). The multiple possible variations that may occur during the delivery of a surgical intervention means that it can be unclear how a surgical intervention should be, or how it has been, delivered in a study. Describing how the study team intended these components to be performed within the study protocol may be a difficult process. It may be necessary to document precisely how each step of the intervention is to be executed within the study, which to many surgeons may be restrictive. Though this may be desirable in an explanatory study (which seeks to assess the efficacy of an intervention in an optimal environment), it can have drawbacks. If the intervention is over standardised, it may not be representative of what happens in real-life practice, making it difficult to generalise the results outside of the study (27).

The study team may alternatively opt for a broad and unrestrictive definition of the complex intervention. This allows the surgeon to determine how the intervention may be delivered. While this may be desirable for a very pragmatic study, where the aim is to emulate the natural variations of real-life practice (30) this too has its disadvantages. If the description of the intervention is too broad, there is a risk of heterogeneous delivery of the surgical intervention and its concomitant interventions, which may compromise the internal validity of the study (where the results of the study are biased because of confounding from other variables that are not the focus of the study). It also makes it difficult to reproduce the intervention, if found to be successful, in routine practice after a study has been completed (31). Regardless of the extent to which an intervention is defined within a study, a further consideration is the extent to which its delivery is monitored.

1.1.2.2 The importance of understanding how a complex intervention was delivered within a study

Establishing how a complex surgical intervention under investigation is delivered within a study is important for study design. In RCT study design it is important to know if the intervention has been delivered as the research team intended (intervention fidelity) (32). Failure to measure intervention fidelity makes it more difficult to accurately attribute RCT outcomes to the intervention itself, because of the uncertainty regarding what was actually delivered. If, for example, a study found no treatment effect, and fidelity was not measured, it is impossible to ascertain whether this is because the intervention was not delivered as intended, or because it was ineffective. It is recognised that it is hard to measure fidelity for complex interventions, because of the greater potential for variation in intervention delivery (33).

In observational study design the aim is to observe and assesses the strength of the relationship between the exposure and presence of outcomes (34). This means directly observing participants in their natural setting as a 'fly on the wall', therefore the intervention's delivery is determined by the preferences of the surgeons performing the procedure and local policies (35). For this reason, observational design requires an understanding of the many ways that the intervention may be delivered in its natural setting. For example, in a cohort study evaluating a surgical intervention, the data collection focuses on capturing the participants' exposure to potential risk factors within the operation to determine which component of the surgery influences outcomes. However, this is a problem if the risk factors are unknown or unexpected. This is a challenge when the intervention under investigation is complex and there are multiple technical components and non-technical components (e.g. concomitant interventions, contextual factors and surgeon factors) that may independently or co-dependently act as risk factors. Observational studies are frequently criticised for being vulnerable to influences by unpredictable confounding factors (15) making it important to anticipate confounding factors and collect data on their presence or exposure. These considerations make understanding the complex intervention under investigation an important step for study design.

1.1.3 Solutions for designing studies evaluating complex interventions

In 2000, the Medical Research Council (MRC) published a framework to recognise the challenges of evaluating complex interventions and support use of appropriate methods to tackle these challenges (36). This has since been updated (2006) and it now explicitly recognises surgery as a complex intervention (25). The MRC provides a framework for considering appropriate methods to evaluate complex interventions and encourages their careful 'development' to improve understanding on how the components of the intervention influence outcomes. However, while guidance exists from the MRC, it has yet to be adapted for surgical interventions. This may be because the content of surgical interventions is sometimes unpredictable or unknown (37) and it is not clear how to apply such guidance to surgical studies. Further attention to this area of research is therefore required. One area where advances have been previously made is where study teams have performed feasibility work.

Work done before a main study can broadly be described as 'feasibility work'. The use of feasibility work in surgical research is gaining ground. For example, qualitative and survey methods were used by the Bluebelle study team to explore current practice and stakeholders' views on 'simple' and 'complex' wound dressings prior to designing a large surgical trial (38). This work highlighted that 'complex' dressings were not used in clinical practice and identified 'tissue adhesive as-a-dressing' as an emerging method of dressing wounds. The Bluebelle feasibility work informed the study design and led to a change in the intervention arms of the study to exclude 'complex dressings' and include 'tissue adhesive as-a-dressing' (39, 40).

Other researchers are using qualitative methods in the operating theatre to provide insights to support the interpretation of study results and inform recommendations about future implementation of the intervention (41).

1.1.4 Collecting data to understand technical and non-technical components of a complex surgical intervention

To decide how to optimally deliver a surgical intervention, we must first identify its components and then describe the possible variations that exist for each component, and then determine which variations are likely to be prognostically important for outcomes. This means it is necessary to design data collection methods to adequately capture the variations in the delivery of an intervention so that they can be considered in the analysis. This is a difficult task and surgical studies are frequently criticised for their failure to do this well and adequately capture how it was delivered. Some forms are overly complex and data often missing and others are woefully inadequate. This may result in the surgical community criticising study results for not being generalisable or a 'true' representation of the intervention's performance (2).

Understanding how the intervention was delivered and in what circumstances is critical for interpreting the findings of a study on a surgical intervention. The data may be used by future clinicians delivering procedures or policy makers and commissioners purchasing care. If not enough is known about how the intervention should be delivered or in what context, there is a risk that the study may fail to adequately describe the intervention or control for potential confounding factors. However, deciding what data to collect to determine the impact of technical variations and non-technical variations is a difficult question. This dilemma has been considered within this Masters of Science (MSc) and undertaken as feasibility work for the CIPHER study.

A recently developed typology by Blencowe et al (2016) provides a framework for use prior to the start of an RCT to standardise the delivery of the surgical intervention being evaluated and to guide its description in the study protocol (42). The typology consists of three parts. Firstly, the study team must describe the intervention, focusing on the technical purpose of the intervention and establishing its component parts. Secondly, a decision is made regarding the surgical interventions desired level of standardisation, and how this should be achieved. Finally, the study team are advised to be explicit about how they will monitor intervention fidelity within their study. Blencowe et al used this typology to guide the design of an RCT on obesity reduction surgery. The By-Band-Sleeve study (43) compared laparoscopic adjustable gastric band, Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy for patients with severe and complex obesity (42).

Roux-en-Y gastric bypass is a complicated intervention and operative steps are not well established (44). Within the first step of the typology, Blencowe et al used qualitative methods to explore Roux-en-Y gastric bypass within its own context, the operating theatre. Using case study methodology, Blencowe et al observed surgery followed by interviews with the surgeons to theoretically deconstruct Roux-en-Y gastric bypass into its component parts and 'key' functions. In the second stage of the typology Blencowe et al established whether each component should be mandatory, optional or prohibited (42), allowing the study team to make decisions about the extent to which Roux-en-Y gastric bypass should be described and subsequently standardised within the By-Band-Sleeve study protocol (44). These methods from Blencowe et al may be useful for determining the components of a complex intervention. However, the Blencowe paper did not translate these ideas into non-randomised work or describe how to specifically develop data collection to establish how the surgical interventions were delivered within the study. This MSc will build on and expand the work by Blencowe et al.

1.1.4.1 Determining how a complex intervention was delivered within a study

As previously discussed in section 1.1.2, establishing how the complex surgical intervention under investigation was delivered within a study is important for both RCT and observational study design. One way to assess how an intervention is delivered is to develop case report forms (CRFs). CRFs are specialised documents used to capture participant data during a study. Using CRFs to document how the intervention is delivered can give insight into what actually was delivered during the study. Some people refer to this as the 'black-box' of a complex intervention. It is increasingly recognised that CRF development is an important step in study design (45, 46). CRFs should be study protocol driven and robust in content. This requires enormous planning and attention to minute detail (46). The development of CRFs that are able to measure how a complex intervention and its concomitant interventions are delivered within a study requires careful planning, development and research into how to optimise the process.

A drawback of using CRFs to assess how the intervention was delivered is that it relies on the self-reporting of the individuals delivering the intervention, who may not have done what they say they have done, and may not have accurately completed the CRF. There are alternative methods that may be used to assess delivery other than self-reporting. These include the use of independent assessors who observe and measure delivery, or using audio/video recording to assess delivery remotely (47). However, these are often impractical as they require significant resources.

1.2 The UK Cohort study to Investigate the Prevention of parastomal HERnia (CIPHER)

The CIPHER study, the UK Cohort study to Investigate the Prevention of parastomal HERnia, is a National Institute for Health Research Health Technology Assessment (NIHR HTA) programme funded study that seeks to identify the risk factors for developing a symptomatic PSH following stoma formation. It has an observational study design and intends to collect information on participants prospectively. The study was scheduled to begin in July 2017 led by Chief Investigator Mr Neil Smart, supported by the Bristol based Clinical Trials and Evaluation Unit (CTEU) and the MRC ConDuCT-II Hub for Trials Methodology Research. This section will introduce the rationale for performing this research and highlight the methodological challenges that face the CIPHER study, thus explaining the rationale for this MSc.

1.2.1 What is a stoma and parastomal hernia?

Having a stoma means having a section of bowel disconnected and routed through an artificially created hole in the abdominal wall. This means that the bowel can empty its contents (faeces) into an external bag. PSH can occur as a complication of stoma formation. A PSH is a swelling around the stoma whereby abdominal contents protrude underneath the skin. Following stoma formation, it is possible that up to 50% of patients develop a PSH (48). While some PSHs are asymptomatic, many are associated with problems. The most common symptoms are pain (35%) and difficulty attaching the stoma appliance (28%), which may result in the leakage of bowel contents (28%) (49). Anxiety and embarrassment associated with PSH can influence sexual function, social interaction, and work (50). Hospital admission may be required if a section of bowel becomes trapped in the PSH, leading to serious complications such as bowel strangulation, obstruction, or perforation. If treatment is required, this usually involves further surgery which can be difficult and does not guarantee success. Surgical treatment of PSH can be elective (planned) for long-standing complications or emergency (unplanned) for complications that must be treated immediately. Mortality is reported in both the elective and emergency setting and further surgical treatment is often required. Prevention of PSH is therefore a priority. Indeed, this was recently highlighted by the Association of Coloproctology of Great Britain and Ireland (ACPGBI). In this survey, healthcare professionals identified PSH prevention as a key future research priority (51).

Both patient and surgical factors may influence the risk of developing PSH. Patient factors are well-known and include advanced age, obesity, wound infection, malignancy, inflammatory bowel disease, immunosuppression and raised intra-abdominal pressure (52) (53) (54). However, the surgical risk factors are less well defined. It has been suggested that the technical risk factors include the location and size of the abdominal wall defect created during stoma formation (53), with some surgeons placing mesh (a sheet of woven material) around a stoma in an effort to strengthen the abdominal wall (55). Other factors that have been theorised to influence PSH formation are whether the operation was planned or unplanned (53), the expertise and seniority of the surgeon, pre- and post-operative stoma nurse consultation and intensive care associated interventions. The surgical techniques for creating a stoma vary considerably (56), but there is almost no high-quality research evaluating whether the risk of a PSH is less with some techniques than others. Where there is research, the results are often conflicting (57). The lack of reliable evidence about the variations in surgical techniques means that it is not sensible currently to perform an RCT comparing one or two surgical techniques. Instead further investigation is required to determine the extent to which individual factors, or combinations of factors, influence PSH development. Further investigation will allow for the identification of areas for future enquiry in an RCT.

1.2.2 Methodological challenges within the CIPHER study

A challenge to identifying the risk factors for PSH development is the complexity of stoma formation itself (Section 1.2.5). Variations in stoma formation may be 'known' (and existing in the literature), or 'unknown' (and absent from the literature). The lack of knowledge regarding the 'unknown' risk factors is problematic for the prospective collection within the CIPHER study. It was considered important to identify and describe these 'known' and 'unknown' variations prior to the start of the CIPHER study, to enable the research team to specify the exact information that needs to be collected in the CIPHER study and design the CIPHER CRFs with an appropriate evidence base. The CIPHER study was therefore designed to include a pre-study feasibility phase. This consisted of work to resolve this methodological challenge and this was supported by the MRC ConDuCT-II Hub. This phase included investigation of the data items to be included in the CRFs to comprehensively determine the technical and non-technical potential risk factors for PSH development.

1.3 Aims and objectives

This MSc aimed to address a research gap in knowledge of potential PSH risk factors, to inform the CRFs for the CIPHER study. It aimed to identify all possible factors that may contribute to PSH formation, and then to produce a pragmatic but scientifically informed list of data items to be collected in the CIPHER study. The CIPHER study was then expected to go on to measure these and to use the data to establish risk factors for PSH formation.

The specific objectives of this MSc were:

- To identify the ‘known’ and ‘unknown’ technical and non-technical factors that may influence PSH formation;
- To use this to create a ‘long list’ of potential technical and non-technical factors that may influence PSH formation;
- To scientifically rationalise the long-list of potential technical and non-technical factors to determine which data items to collect in the CIPHER study CRFs using consensus methods.

1.4 Thesis synopsis

This MSc had four stages. First, a literature review to identify the ‘known’ factors that may be relevant to PSH development. Second, a qualitative study consisting of non-participant observation and digital video capture of stoma formation in theatre, followed by in-depth semi-structured interviews with operating surgeons and stoma nurses to uncover the ‘unknown’ factors of interest. Third, amalgamation of the variations identified in the first and second stages of this MSc to create a long-list of potential variations that may influence PSH development. Finally, rationalisation of the long-list of factors using consensus methods to determine the final data items of interest to collect in the CIPHER study CRFs.

CHAPTER 2. METHODS

This chapter will discuss the methods used for each stage of the project.

Section 2.1 provides a brief overview of the methods used in the MSc.

Section 2.2 discusses the first stage of work, the literature review, with an in-depth description of the adopted search strategy and approach to analysis.

Section 2.3 considers the second stage of the project, the mixed qualitative methods work, incorporating interviews with healthcare professional participants and in-theatre non-participant observations of stoma formation.

Section 2.4 describes how the first and second stages were drawn together to create a 'long-list' of results that was used to inform a consensus meeting.

Section 2.5 discusses the consensus meeting methodology where the content of the CIPHER study CRFs was discussed and agreed.

2.1 Overview

The overall methodological approach taken in this MSc builds on Blencowe et al's (42) use of qualitative methods in the operating theatre to deconstruct a complex surgical procedure for use in a RCT. Qualitative methods enabled the trial team to determine the components of the complex intervention and subsequently standardise the surgery under investigation within the study protocol (44). These methods were adapted and applied to this MSc to investigate 'known' and 'unknown' variations related to stoma formation surgery that may influence PSH development, and thus should be collected in the CRFs for CIPHER. 'Known' variations were defined as hypotheses or theories that are already reported in the existing body of literature on PSH prevention, and 'unknown' variations as those that were identified in this study that have not been previously reported.

Others performing qualitative methods within the operating theatre include Randell et al. Randell et al have a published a protocol detailing the methods for a proposed realist process evaluation of a surgical intervention (robotic rectal cancer surgery) (41). A realist process evaluation incorporates qualitative methods of interviews, ethnographic observation and video to create context-mechanism-outcome (C-M-O) configurations of theory to improve understanding of the mechanisms through which the complex intervention achieves its outcomes (58). Realist process evaluations aim to have an explanatory focus (59). The aim of this MSc was to explore and describe the possible variations of stoma formation to inform the design of CRFs, not to provide an explanatory element to support the interpretation of the results of the main study. A realist process evaluation was therefore beyond the scope of this body of work although it would be relevant to use in a future main study to examine the implementation of an intervention.

2.2 Stage 1 Literature review

2.2.1 Aim

A literature review was undertaken with the aim of i) identifying the 'known' factors that may influence PSH formation, and ii) informing the topic guide and observation schedule for the qualitative work undertaken in the next phase of the research.

2.2.2 Literature review

The necessary first step for this research was to determine what is already 'known' about the factors surrounding stoma formation surgery that are hypothesised to influence PSH development. The most appropriate method to achieve this was by performing a review of the existing literature. Traditionally this would be performed as a systematic literature review (SLR).

2.2.2.1 Systematic review methods

A SLR is an established methodological process that aids researchers to balance and summarise the evidence to answer a specific question. An SLR is defined as 'a replicable, scientific and transparent process that aims to minimize bias through exhaustive literature searches of published and unpublished studies and by providing an audit trail of the reviewer's decision, procedures and conclusions' (60). Its specific methods have been widely adopted as a tool for reducing the researcher's bias when considering the existing evidence. In the medical field, systematic reviews have become deeply embedded in evidence-based approaches and are well suited to the field of medicine, which often seeks to balance the evidence to answer the question of 'what treatment or intervention is the most effective?' However, there are limitations and drawbacks to SLRs. A key drawback of the traditional SLR is that they can be time-consuming and not always practical to perform.

For this stage of research the aim was to exhaustively identify "known" factors associated with stoma formation surgery that are hypothesised to influence PSH development, as reported in the literature. This is a goal that would not easily be answered with a SLR for two key reasons. Firstly, designing a search strategy to achieve this aim was deemed to be difficult. A formal database search using search terms 'stoma' and/or 'parastomal hernia' was likely to yield many abstracts (of which only a small proportion were likely to be relevant) all of which would have then needed to be screened in full as the detail this literature review was interested in was likely to be missed by screening abstracts alone. Secondly, an SLR intends to identify high-quality evidence and may exclude low-quality studies or publications that fall outside of the 'study' definition such as letters, commentary and editorial pieces. There was therefore a risk that an SLR could exclude articles containing the data of interest on the intricacies of stoma formation. To this end, the first stage of this research adopted a snowballing method to perform the literature review, as this was considered to be better suited to the needs of the research question.

2.2.2.2 Snowballing methods

Snowballing initially involved identifying an index paper(s), a high-quality article in or around the topic of interest. Following this, a review of the index paper's citations was performed as a method of identifying and retrieving further relevant articles (backward snowballing) (61). The process was then implemented in reverse (forward snowballing) by finding articles that cited the index paper, as a method of finding more contemporary articles (62). Following this another index paper was selected and snowballing begins again. This process is demonstrated by Figure 2.

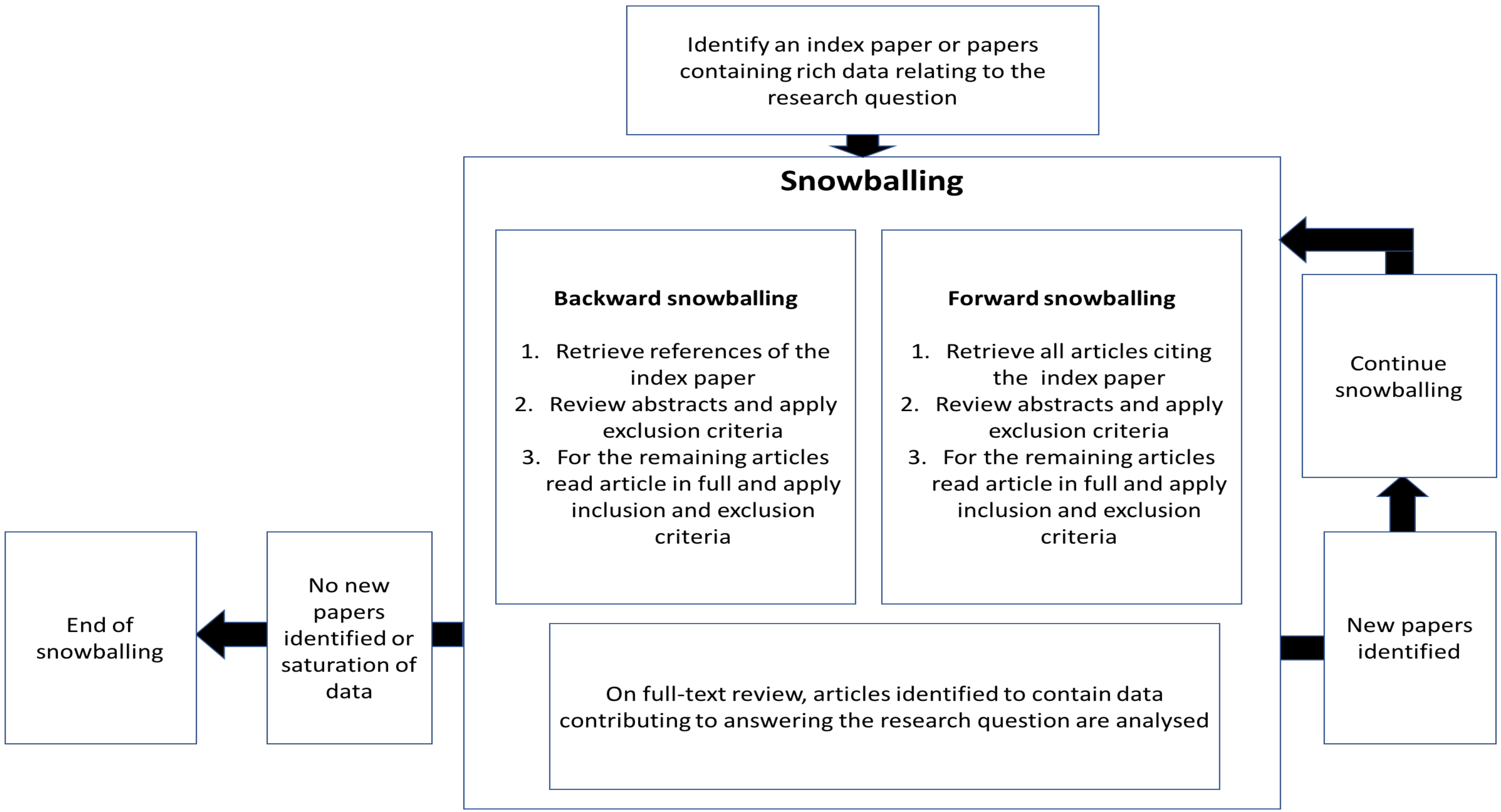

Figure 2: Flow chart demonstrating the snowballing process reproduced with permission from Wohlin (2014) (61)

Snowballing had the following benefits: i) better identification of studies from all levels of the hierarchy of evidence including secondary studies, case series, protocols and descriptions of historical practice, ii) lower yield of results that enabled a more in-depth analysis of the full-text, iii) allowed for the identification of obscure data e.g. through personal knowledge and expert recommendation (63), and iv) pragmatic benefits that included being more time efficient and requiring fewer resources because a snowballing strategy provided relevant abstracts, rather than the large number of irrelevant abstracts identified using SLR methods.

2.2.3 Search strategy

An SLR by Shabbir et al (55) was chosen as the first index paper: the starting point for the review. It was selected because it was a comprehensive, recent, well performed and highly-cited systematic review. Once the process of snowballing had been completed for Shabbir et al, a second index paper was selected: Aquina et al, 2014 (57). Aquina et al, another SLR, was identified through the forward snowballing from Shabbir et al, 2012. It was selected to be the second index paper using the expert knowledge of supervisor Miss Natalie Blencowe (NB) who considered the article to be of high-quality and well regarded within the surgical profession. It was also recent, included rich data within the full-text when analysed, it referenced different articles from Shabbir et al, and its inclusion broadened the literature review.

To complement the snowballing strategy, active researchers within the field of PSH prevention (Mr Shabbir, Mr Smart (NS) and Mr Bransdma) provided additional pertinent literature. This identified two additional relevant RCTs (64, 65).

Snowballing was facilitated via Google Scholar's citation tracking service. It was important to review one citation at a time and record the decision-making process in a traceable manner. The snowballing process was recorded in an excel tracking document that recorded whether each citation was excluded or included.

2.2.4 Study selection

Any article that contained text documenting surgical steps of stoma formation or theories surrounding either technical or non-technical factors that may influence PSH development were included. Articles not written in English or not concerning abdominal stomata were excluded (e.g. urostomy). There was no limit by year of publication or study design.

2.2.5 Data extraction

There was no pre-defined data collection form and no assumptions were made about what data to extract. If relevant text was identified concerning variations on stoma formation or factors that may influence PSH development the full-text was imported into NVivo, a qualitative analysis software (66), and underwent the process of coding. NVivo is further discussed in Section 2.4.7.

2.2.6 Analysis

A qualitative content analysis was used to analyse the included articles. Qualitative content analysis is a method of analysing text that involves the assignment of categories to passages of text through the coding (67). Articles were read and re-read in full to identify sections of text that either described a variation in surgical technique for stoma formation, or theories and ideas about PSH causation or prevention. The identified text within the article was then coded: a process whereby short descriptive word(s) were applied to encapsulate the meaning of sections of text, acting as a shorthand device to label, separate and organise the data (68). The nature of coding is in a constant state of revision and refining as new data emerges and adds to the understanding of theme phenomenon. Data were coded line by line as demonstrated in Figure 3. As coding proceeded, similar codes were arranged into themes (i.e. connected ideas). In initial stages, multiple codes were generated about variations in stoma formation and other factors related to PSH development. While creating codes a process of making connections between codes, organising the codes into themes, category themes and overarching category themes began. This coding hierarchy is demonstrated by Figure 4, where the use of mesh in the primary stoma formation became an overarching category theme for multiple category themes and themes. The coding framework evolved with continued review of articles.

Verbatim text extract from Shabbir et al, 2012

"Mesh insertion at the time of primary stoma formation was first described by Bayer et al. in 1986 [18]…There is variation in where to place the mesh, whether intraperitoneal, preperitoneal or subcutaneous."

Individual code	Text coded
Use of mesh to prevent PSH	("Mesh insertion")
Location of mesh placement	("where to place mesh")
Mesh placed in the intraperitoneal space/IPOM	("intraperitoneal")
Mesh placed in the perperitoneal /sublay/retrorectus space	("perperitoneal")
Mesh place in the subcutaneous/overlay space	("subcutaneous")

Figure 3: Creation of codes

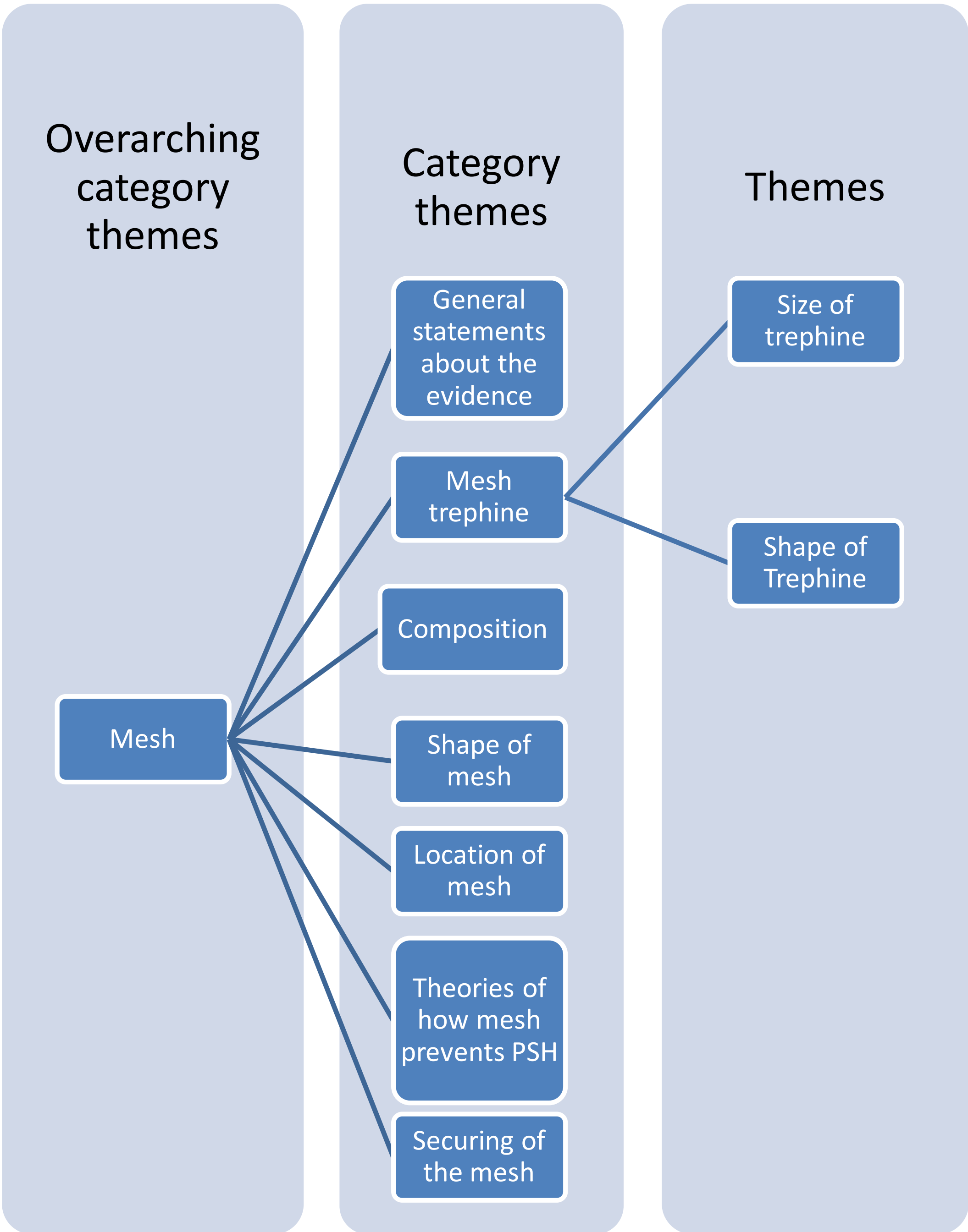

Figure 4: Example of the coding framework for mesh trephine size

The process of snowballing, data extraction and coding continued until either i) no new papers were identified using forward and backward snowballing, or ii) data saturation was achieved. The point of saturation was defined as the point where further articles were no longer creating new codes or further illuminating the existing themes.

The point at which data saturation was reached was corroborated by a second reviewer (NB), which involved coding further articles. If further new codes were identified, then the end point had not been reached and thus further articles were retrieved. This was performed twice and the decision to cease coding was made after the final article yielded no new codes.

The final coding framework consisted of multiple overarching category themes, category themes and individual themes. From this an extensive list of themes on the known potential variations in stoma formation surgery and other factors that may influence PSH development was created. This was used to inform the observation schedule and topic guide for the next stage of research. The development of these documents will be discussed in Section 2.4.3.

2.3 Mixed qualitative methods

This section describes the mixed qualitative methods used to comprehensively investigate the 'unknown' factors that may influence PSH formation. It is possible that many 'unknown' variations of stoma formation exist within surgical practice that are not reported within the literature because it is a complex procedure. There is no universally standardised method of creating a stoma, and one surgeon will not necessarily know what another is doing. It is known that surgical practice is often based on anecdotal experience (69) (e.g. previous techniques that had and had not worked in the past). As such, there is likely to be a high degree of variation in stoma formation techniques.

2.3.1 Aims of the mixed qualitative methods research

The overall aim of the mixed qualitative methods work was to investigate the 'unknown' variations of stoma formation. This was broken down into two parts; i) investigate how stomas are formed within their naturalistic setting (the operating theatre), with the objective of identifying technical variations in stoma formation, and the non-technical factors that might influence PSH formation; ii) To understand health care professionals' practices and views and beliefs about factors that influence PSH formation.

2.3.2 Qualitative methods of data collection

Research can generally be divided into qualitative and quantitative approaches. While they both may inquire about similar topics, each is concerned with answering different types of research questions (70). Quantitative research is typically more suited to investigate queries like the prevalence of a disease, whereas qualitative research is better matched at assessing the impact the disease has on a patient's experiences and life. Qualitative research is an umbrella term for a heterogeneous group of methodologies that focus on the exploration of "real life" behaviour by studying phenomena in-depth, in their natural setting (71, 72). It has a tendency to be explorative as data analysis is largely inductive, allowing meaning to emerge from the data (71). It is valuable for generating theories and hypotheses (73) when there is little or no prior research on a topic and is useful for understanding groups or individuals attitudes and beliefs (74).

Determining the 'unknown' potential factors that influence PSH formation therefore required a qualitative approach, as the aim was to uncover practices and behaviours that the researcher(s) might not have anticipated, as well as understand key stakeholders' perspectives. This thesis employed mixed qualitative research methods including:

a) non-participant observations, to address the aim of exploring stoma formation practices in its naturalistic setting (the operating theatre). This consisted of direct observation of stoma formation in theatre as well as digital video recording to determine what surgeons do in the real-life setting, and

b) semi-structured interviews with surgeons and stoma nurses, to address the aim of exploring the reasoning behind their practices and theories around factors that influence PSH formation.

These methods were deemed to be the most appropriate for achieving the research aims and objectives of documenting and understanding practices and beliefs. Another method that could have been considered for this research was surveying the surgeon and stoma nurse population. A potential benefit of this is that it may have been easier to glean views from a larger sample, and allow for generalisation of findings. However, survey methods would not have captured unknown or personal phenomena, as their design is based on existing knowledge and assumptions and people are often reluctant to report details of sensitive personal issues. This stage of the project aimed to build new knowledge and insights that have not previously been reported in the literature.

2.3.2.1 Non-participant observation

Observation methods can be described as the study of social interactions, behaviours, and perceptions that occur within groups, teams, organisations, and communities (75). Observation methods take place in the natural setting (76) and are useful as they allow for the generation of a rich understanding of a phenomenon and its subtleties in different contexts (75). Observation can be participant or non-participant. Participant observation involves direct observation while the researcher actively participates in the study community (77), this requires the researcher to immerse themselves fully into the daily life of the group being studied. While participant observation might produce rich data it may not always be feasible or appropriate given ethical issues, constraints on time and funding (77, 78). Non-participant observation involves the research acting as a "fly on the wall" as an outsider watching recording activities and interactions (79).

This research used non-participant observation as a method to study stoma formation in its natural setting. This was selected due to the ethical implications of the researcher, Charlotte Murkin (CM), participating in surgery as well as time restrictions as CM would have been unable to fully immerse herself into multiple different surgical teams. The non-participant observation in this research consisted of two data collection methods: direct observation and digital video data capture. The benefit of directly observing surgery is that it enables the documentation of verbal and non-verbal communication, as well as contextual factors that would otherwise be unrecorded using digital video data capture in isolation. The operation was additionally digitally video recorded so that the observation could be seen from a different angle, which was particularly important in this setting because surgeons and equipment surrounding the operating table could obstruct views of the procedure being performed. Digitally recording the observation also meant that the operation could be watched again, relieving the time pressure interfering with documentation. This was done to enhance the technical detail in the observation, as CM may have missed details of the operation while writing. This also enabled CM more opportunity to focus on documenting the contextual aspects of the observation at the time (i.e. factors that were less likely to have been captured on the video). A further benefit of digitally recording the operation is that it allowed a second researcher to analyse and code the observation, enhancing the rigor of this study.

2.3.2.2 Semi-structured interviews

Interviews are the most commonly performed method of data collection in qualitative research (80). Interviews were employed in this research to explore clinical professionals' perspectives on stoma formation practices, and risk factors for PSH formation. The interviews had three components: 1) confirm, refine and refute the 'known' factors identified in the literature work, 2) uncover and explore 'unknown' technical variations in stoma formation and non-technical variations that may influence PSH development, 3) discuss what was witnessed in the non-participant observation to seek clarity and explanations of observed practices.

Interviews may be structured, semi-structured or unstructured (81). Structured interviews follow a standardised set of questions (determined by the topic guide) with generally little room for variation and requires a well-developed understanding of the topic at hand (82). While structured interviews are efficient they limit opportunities for the respondent to express ideas not directly related to the fixed questions (81). Unstructured interviews do not follow a topic guide and rely on a good rapport with the respondent to drive discussion. Unstructured interviews are useful when the researcher's understanding of a topic is still evolving but often requires multiple meetings with the respondent (82). Semi-structured interviews are guided, but not restricted, by a topic guide that outlines topics to discuss. Semi-structured interviews were selected as the most appropriate approach to exploring stakeholders' perspectives on factors that can influence PSH formation, because there was a desire to explore key topics (informed by the literature), with sufficient flexibility to pursue new ideas/relevant topics as they emerge through discussion with the participant. The semi-structured interview approach allowed CM to explore some broad areas informed by the literature review work, with the freedom to follow trajectories of conversation that were not included in the topic guide. This was useful as there was only one opportunity to interview respondents, given time constraints of the research project and the stakeholders of interest.

The semi-structured interviews were designed to contain open-ended questions and have a non-rigid framework, enabling CM to readily pursue new lines of enquiry that might arise from informants' responses (83). Maintaining sufficient flexibility was thought to be ideal for this exploratory stage of the research, as there was an intention to elucidate ideas/theories that had not been encountered elsewhere (e.g. in the literature)(84). Semi-structured interviews were principally performed with surgeons involved in the care and prevention of PSH. However, to better develop an understanding of theories, interviews were also held with healthcare professionals not directly involved in stoma formation (in this case, stoma nurses).

2.3.2.3 Benefits of using a multi-method approach

A multi-pronged approach to understand stoma formation was considered important because any one method alone has limitation. For example, using interviews alone would have been limited to relying on what surgeons say they do in the operating theatre (rather than gaining first-hand what they actually do). Therefore, it was valuable to additionally investigate stoma formation in its naturalistic setting (the operating theatre) to challenge and enhance ideas discussed in the interviews. Furthermore, interviews alone would not necessarily have captured some of the contextual 'in-theatre' factors that might influence PSH formation. Conducting observations alone would have been limited, because CM would not necessarily have understood the reasons why certain practices/behaviours occurred. Observed practices needed to be further explored with the operating surgeons to understand the reasoning behind their methods (or their views about factors that influence risk of PSH formation).

Combining interviews with observations provided a basis for a more comprehensive understanding of events that transpire in the operating theatre, practices for stoma formation, the reasons underpinning these practices, and stakeholders' views/beliefs about factors that influence PSH formation. Performing dual qualitative methods of data collection has the ability to support and corroborate emergent findings through triangulation. Triangulation is a process where the researcher is able to compare the results of different forms of data collection to look for patterns of convergence or confirmation (85). Denzin (86) proposed that there are four forms of triangulation; the use of multiple sources; the use of multiple methods; the use of multiple investigators; and the use of multiple theories. This research was triangulated through using multiple sources and mixed qualitative methods of data collection.

2.3.3 Development of the observation schedule and topic guide

The coding framework developed during the literature review was also valuable for the mixed qualitative methods. It was used to develop tools to simplify and enhance the data collection during the non-participant observations and semi-structured interviews. Specifically, it was used to describe the main steps of stoma formation and inform the headings of both the observation schedule and inform questions in the topic guide (Appendix 1 & Appendix 2 respectively).

2.3.3.1 Observation schedule

The observation schedule is a template used to guide the documentation of the direct observation of stoma formation in theatre. The coding framework enabled the lead researcher (CM) to structure the observation schedule and allowed for systematic documentation of the stoma formation being observed. For example, the following headings were used as page titles to chronologically document the surgical stoma formation being observed:

- Context of stoma formation (e.g. location, time, indication, surgeon characteristics)
- Skin incision
- Abdominal wall incision
- Mesh
- Exteriorising the bowel
- Other

Inclusion of the 'other' heading was particularly important, as this encouraged the researcher to capture other potentially important details that might not have been anticipated, thereby reducing the likelihood of the findings being constrained and restricted to pre-determined topics (as broad as those topics were). The aim of the observation schedule was to provide a structure for documenting two overarching areas: i) the surgical methods used by the surgeon to create the stoma, and ii) any contextual considerations, such as the surrounding environment (e.g. time of day, urgency of the operation), surgeon factors (e.g. speciality, grade, level of tiredness), and patient factors that became apparent (e.g. co-morbidities). The observation schedule was useful as it aided documentation of variations within the broader steps of stoma formation as the operation progressed rapidly and it was difficult to make detailed notes.

The observation schedule was piloted by CM, who observed a surgical stoma formation at the Royal Devon and Exeter (RDE) Hospital on the 1st of August 2016. This observation was not included in the final analysis but resulted in the amendment of the document. Amendments included additional blank pages for field notes and the refinement of the prompts and probes to be more general, as CM found too much text on the observation schedule to be too distracting. The final observation guide can be seen in Appendix 1.

2.3.3.2 Topic guide

Interviews with surgeons and nurses were supported through use of a topic guide: a series of open ended questions and prompts/probes, arranged into broad topics to guide the interviewer (CM). The topic guide was important for ensuring that a basic set of similar topics were consistently covered across interviews, to aid later comparison across informants' responses. Bryman (2008) (87) summarises a process for creating topic guides through a series of steps illustrated below in Figure 5 .These broad steps helped to inform the topic guide. The first three steps of Bryman's process were achieved during the literature review, with the interview topics (step 3) derived from the category themes identified in the literature. Initial questions were formulated with input from this MSc's supervisors NB and Dr Leila Rooshenas (LR) with the intention to use open ended questions to facilitate the emergence of relevant discussion that may diverge from the topic guide (88).

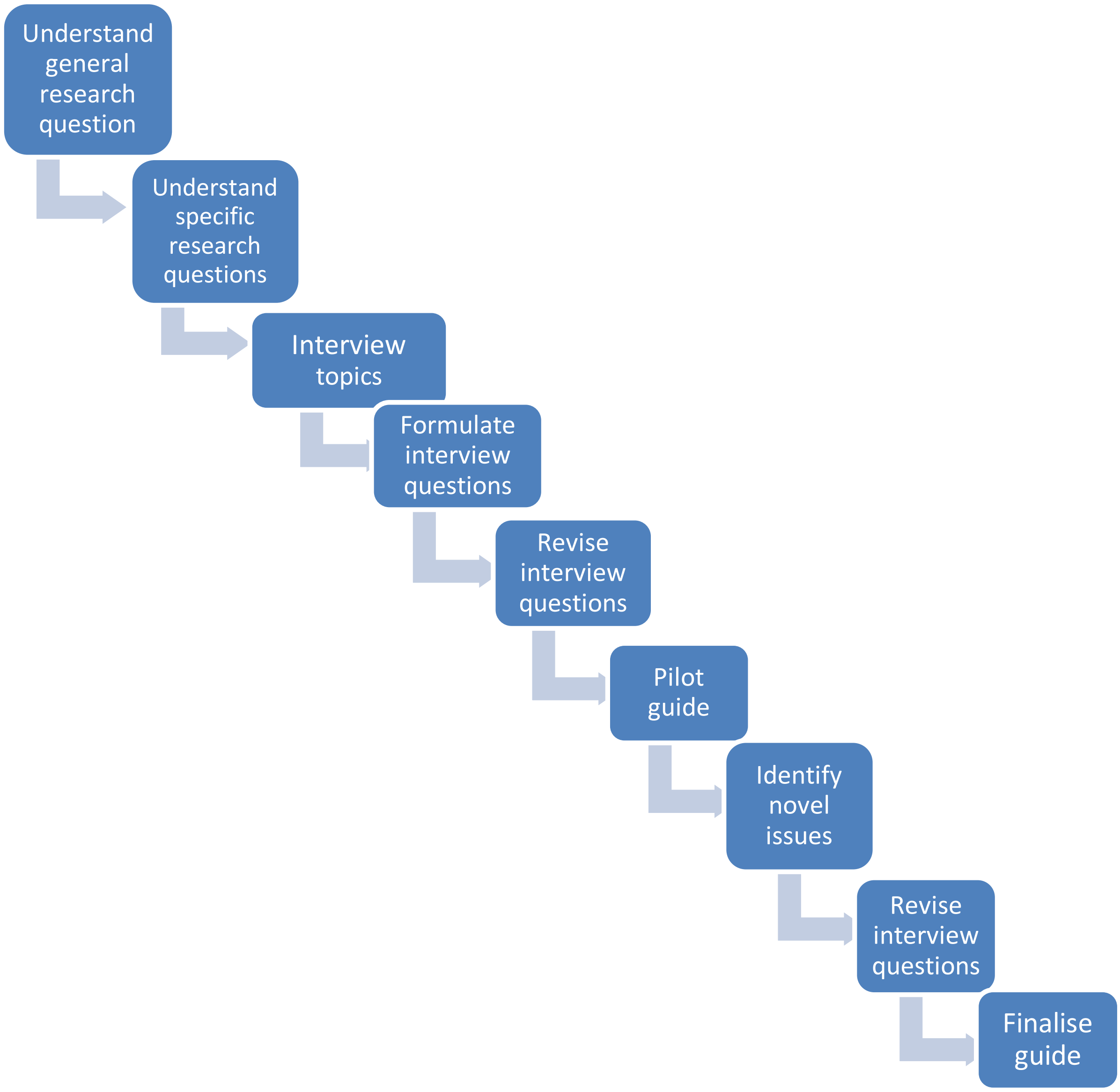

Figure 5: Bryman's process of topic guide creation. Reproduced with permission from Oxford University Press (89)

The topic guide (Version 1.0, Appendix 3) was then piloted in two interviews with surgical trainees (not included in the analysis) to test for flow, the relevance of content, and whether the questions provoked responses/discussion. Version 1.0 of the topic guide consisted of multiple open-ended questions based on the broad overarching categories from the literature. These included: Variations in technique; surgical techniques that affect PSH development; factors affecting choice of surgical technique; contextual factors affecting PSH formation; patient factors. Following piloting alterations were made and these questions were revised to be fewer in number and include more themes identified from the literature review as 'probes' for the participants to promote further discussion following the open-ended questions (Version 2.0, Appendix 4).

The topic guide (Version 2.0, Appendix 4) was updated iteratively as the interviews and observations proceeded, as new lines of enquiry emerged through discussions with participants and observed practices. The final topic guide (Version 3.0, Appendix 2) comprised fewer less specific questions to guide the flow of the interview, and more prompts and probes containing the specific themes identified through the literature and iterative interviews. As such, contrary to Bryman's (2008) indication that the topic guide is finalised after piloting, the topic guide evolved throughout the data collection process.

2.3.4 Participating centres

The interviews and direct observations were performed in two centres: RDE and University Hospitals Bristol NHS Foundation Trust (UHB). These centres were selected for practical reasons as the research team had professional contacts in both trusts making identification of Principal Investigators (PI) simpler. They are also geographically close therefore reducing the time and cost of travelling between sites.

2.3.5 Sampling strategy

The focus of qualitative research is to perform an in-depth exploration of the attitudes and ideas that govern individuals' behaviours, rather than being able to generalise the results to the wider population. Random sampling methods therefore have little role in qualitative work and efforts instead are focused on seeking out 'information rich' individuals/cases (90). The literature describes five major methods of sampling in qualitative research (91). Two frequently used methods are convenience and purposeful sampling. Convenience sampling involves selecting the most accessible individuals (92), based on a first-come, first-served basis (91). This method is often inexpensive, quick and simple to perform however it may result in poor quality data that lacks intellectual credibility (92). The most typically used method of sampling in qualitative research is purposeful sampling, where participants are strategically selected based on particular characteristics that are relevant to the research question (89, 92). Purposeful sampling is beneficial for identifying participants that are especially knowledgeable about or experienced with the phenomenon of interest for the most effective use of limited resources (93, 94). The sampling of healthcare professionals in this study was based on a 'key informant' purposeful approach. A key-informant approach is a type of purposeful sampling where individuals with exclusive specialist expertise are selected as the most productive sample to speak to and observe (92).

When identifying surgeons to participate we intended to include surgeons of all grades. In practice, the majority of surgeons who form abdominal stoma electively (in the planned, non-emergency setting) are colorectal specialists. Colorectal surgeons would also be involved with the majority of PSH clinical presentations that warrant surgical repair. This group may be considered to be the expert group, who form the majority of stomas and are most familiar with the existing and emerging literature on stoma formation and PSH. Colorectal surgeons were therefore thought most likely to have developed ideas about PSH prevention. Other specialists that form abdominal stomas are the upper gastro-intestinal surgeons. This is usually as part of their on-call (out of hours emergency care) commitments. Forming an abdominal stoma while on-call often means the stoma is formed in the emergency setting and therefore these are rarer. As these surgeons also form stomas it was thought that it would also be beneficial to try to recruit them, as they may use different methods. A range of healthcare professionals from both centres were interviewed and observed, up to the point of saturation, where during analysis no new themes were uncovered and additional data was not adding any further explanatory or descriptive benefit.

2.3.5.1 Sample

Non-participant observation

There was no set target sample, as is characteristic of qualitative research, however it was expected that five to ten observations of different surgeons would be achievable. It was predicted that this sample would yield rich information and this was anticipated to be a realistic number, based on the research experience of NB who has previously used this methodology in the theatre setting (44), and the time constraints of the project. The number of observations was restricted by the number of cases of stoma formation performed across the two participating centres during the data collection period (i.e. three months) as well as the number of surgeons creating abdominal stomas within the centres. To enhance the diversity of the sample each surgeon would only be observed once.

Selecting which operations to observe depended on two considerations: the operating surgeon, and the patient undergoing surgery. Surgical consultants and surgical trainees of all grades and specialty who performed abdominal stomata were eligible (i.e. no exclusions, based on specialty or grade). The aim of this was to observe stoma formation performed by multiple different surgeons, rather than the same surgeon creating multiple stomas.

The eligible patient population for the observed stoma formations reflect the population eligible for the CIPHER study. This constituted patients aged 18 years or over who required an ileostomy or colostomy. Stomas formed for any clinical reason were included, in both the planned and unplanned setting. Patients whose surgeon intended to form a urostomy were excluded.

Semi-structured interviews

The same sample of surgeons eligible to participate in the non-participant observations were considered for the semi-structured interviews. The intention was to interview the operating surgeon at a convenient time following each non-participant observation.

Stoma nurses were identified as another group of 'key informants' for potential interview participation, because they contribute to post-operative care and often are the first to observe and diagnose patients with a new PSH. Stoma nurses also have an important pre-operative role in marking the site for prospective stoma formation (a 'known' theory derived from the literature that is thought to impact PSH development). As such, stoma nurses were thought to possibly have views/beliefs about the technical and non-technical risk factors for PSH. Stoma nurse interviews were considered complimentary and so did not require a linked observation.

2.3.6 Recruitment

Healthcare professional participants were identified through local PIs. Once introduced via the PIs, CM contacted the healthcare professionals who were willing to participate via email to provide further information by providing a Healthcare Professional Information Leaflet and inviting them to take part in an interview. If there was no response CM contacted them a further time a week following the first email. Prior to being interviewed or observed the healthcare professional participants were asked to complete a consent form and were given a copy to retain for their own records.

Participating surgeons were asked to identify and contact potentially eligible patient participants. This was done through their secretaries or via a telephone call to request permission for CM to make further contact. CM then telephoned or visited the potential patient participant to discuss the study and to deliver by hand or post the Patient Information Leaflet. Patients were consented to being observed on the day of surgery. Patients were also consented with the local trusts medical illustration consent form. A copy of both consent forms was retained in the notes.

2.3.6.1 Ethical considerations

This study gained National Health Service (NHS) Research and Ethics Committee approval from the East Midlands - Nottingham 1 Research Ethics Committee [ref 16/EM/0155] on the 1st of June 2016. Ethical and local agreements were in place for both NHS trusts prior to commencing the research.

2.3.6.2 Confidentiality issues

Confidentiality was maintained throughout the study. Participants were allocated a unique study identification number to maintain anonymity. Digital video recordings and transcripts were anonymised using the unique study identification numbers and stored in a protected folder on the University of Bristol server, which was only accessible to the research team. Participant names were stored separately in a study folder kept in a locked filing cabinet at the Bristol Population Health Science Institute, accessible only by CM.

2.3.7 Data collection

2.3.7.1 Non-participant observation

Two methods of data collection were used during the non-participant observations. Digital video data capture and direct observation that was documented as field notes on the observation schedule.

Digital video data capture

Each centre had its own policy regarding digital video data capture and so methods used to digitally video the stoma formations differed. Methods were determined through discussion with the local imaging departments. In the RDE the trust approved a portable digital video recorder that was given to a junior member of the surgical department to manage beside the operating table. The above-head theatre camera was also used, which was managed by a theatre nurse. Both digital video recorders were used for all cases in the RDE as they provided different views, enhancing the quality of the observation.

In the UHB, a member of the medical illustration team recorded the procedure using their own equipment. Both trusts used the same portable digital video recorder operating procedure where the recorder was secured on a stable tripod, at a safe distance (determined by the lead nurse and lead surgeon) from the operating table. The video recorder was turned on when the steps of stoma formation began and stopped upon completion, usually when the stoma bag was attached. Digital video data capture focused on the abdomen alone, capturing only the surgical steps of stoma formation.

The overhead digital video recording was removed with an encrypted hard drive immediately after completion of the surgery. A copy of the recording was kept by the trust. The file on the encrypted hard drive was subsequently uploaded to the secure University of Bristol database and deleted from the encrypted hard drive as soon as possible. The same method was used for the portable digital video recorders and the medical illustration teams retained a copy of the recording for their records

Direct observation

Field notes were made on the observation schedule by CM. Field notes consisted of the observed steps taken by the surgeon to create the stoma and any contextual details about the operation that may affect the stoma formation. Field notes included drawings to enhance CM's written observations.

Baseline information was also documented for the patient (e.g. age, sex, co-morbidities), the operation (e.g. planned or unplanned, name, duration, timing) and the operating surgeon (e.g. age, gender, number of years of training, specialty), providing additional context to the observation.

Post-observation notes

CM wrote a detailed account following each of the observations, using the field notes on the observation schedule as an aid. This was done as soon as possible following the observation. The detailed accounts were then aligned with the digital video data capture to construct a step by step documentation of the procedure.

The digital videos were viewed in their unedited form independently by NB and CM, and notes were taken to document the steps from the beginning of the procedure until the end. This required CM and NB to watch and re-watch the digital video recordings, taking note of movements, instruments and actions. The benefit of having two independent step by step documentations for each of the digital video data captures was that it enabled CM to compare her interpretations of the recordings with that of a more experienced surgeon. NB is a surgeon with extensive training and knowledge of anatomy. She was able to easily identify and name surgical instruments which was considered to improve the quality and accuracy of the step by step documentation of the non-participant observation. This helped to enhance the rigour of the data collection and analysis process.

The detailed account created by CM from the observation schedule field notes was only available to CM when performing the step by step documentation of the digital video data capture and not NB. Any discrepancies between NB's and CM's step by step documentation of the digital video data capture were discussed between the two and resolved by examining CM's detailed account of the direct observation. The documentation of the digital video data capture created by CM and NB describing was then imported into NVivo software to be analysed.

2.3.7.2 Semi-structured interviews

Interviews with surgeons were ideally held after direct observation in theatre so that CM had the opportunity to ask questions regarding what was observed in theatre. This was to add explanatory weight to the practices observed and challenge inconsistencies between what was observed and what was said. However, this was found to be not possible to arrange due to surgeon time constraints and the infrequency of scheduled and emergency stoma formations. Subsequently, the timing of surgeon and stoma nurse interviews was based on what was mutually convenient for both CM and the respondent and observations and interviews were often performed independently of each other.

Interviews were held in pre-agreed mutually convenient locations, usually the surgeon or stoma nurse's office at the hospital.

All interviews were audio recorded using a discreet digital audio-recording device. The participant was always made aware prior to the beginning of the interview of the intent to audio record and details regarding this were included in the information leaflet. Specific consent to audio record was also included in the consent form.

The benefit of audio recording the interviews was that it enabled CM to engage in the interview naturally, without relying on excessive note taking. This helped build rapport and encouraged active listening, both of which stimulated discussion and enabled new topic and issues to be explored more fluidly.

Field notes were made during and after the interviews, to cover contextual details such as if interruptions, whether interviews were linked to observations, and any non-verbal information, (e.g. a hand-drawn image being used to augment explanation of a topic). Reflexive notes related to CM's experience of the interview, such as any aspects that were challenging, were also recorded to help refine the topic guide and future data collection processes.

2.3.8 Transcription

2.3.8.1 Semi-structured interviews

All interview recordings were transcribed verbatim. Transcription is the transference of spoken language with its particular set of rules to the written word with a different set of rules (95). While the transcripts did not undergo linguistic analysis, verbatim transcription was useful when utterances had meaning (e.g. "mmmm" being given as a positive answer to a question). Transcription was performed as soon as possible following the end of the interview so that analysis could occur prior to the next interview.

There are known benefits to researchers transcribing their own audio recordings including that it allows them to be as 'close' to the data as possible, helping the researcher to become more familiar with the data at an early stage. However, as CM has no prior experience in transcribing it was deemed too time consuming for her to do so. Furthermore, to enable this research to inform the CIPHER study additional time constraints meant that this was impossible. All of the audio recordings were therefore transcribed using a third-party company.

Once transcribed CM read the transcription whilst listening to the audio-recording to check for misinterpretation or inaccuracies. Poland (1995) provides examples of human error in the transcription process using them to illustrate how transcription cannot reflect the real interaction. Misinterpretations were frequent when the surgeons used advanced medical terminology. Using CM's knowledge from the interview and own medical background, these errors were amended on the transcription in red font.

2.3.9 Data analysis

As data collection progressed efforts were made to analyse the data immediately after each interview or observation was completed. This enabled the findings of that interview or observation to be further explored and scrutinised in the ones that followed. This was done by editing the topic guide or CM paying additional attention to aspects that were previously not clear.

2.3.9.1 Choice of analytical approach

Data from interviews and observations were analysed thematically. The approach to thematic analysis was based on the principles of grounded theory. Grounded theory aims to develop theories that are 'grounded' in the data (96). Techniques for building theories rely on the process of 'constant comparison', where data that have already been coded are revisited in light of new themes arising from newer data (97). This backwards and forwards process means that the coding frame for a data set constantly evolves, until the point of saturation.

Consistent with grounded theory, a mostly inductive approach was employed when analysing the transcripts from the semi-structured interviews and the documentation detailing the non-participant observations. This allowed themes to be data driven because CM had no prior theoretical knowledge about the 'unknown' variations of stoma formation. However, due to the prior literature review, CM had some knowledge of the key 'known' theories (e.g. use of mesh), but CM was nonetheless able to inductively add to theses 'known' themes with new layers of complexity that came from coding the interviews and observations.

2.3.9.2 Process of conducting the analysis

The thematic analysis of both transcripts from the interviews and step by step documentation from the non-participant observation contributed to the same data bank. First, data were coded line by line, as previously discussed in Section 2.3.6. Each time CM came across a section of transcript or observation documentation that could not be encapsulated by an existing code, a new code was created. Data were added to the data bank through further sampling until the coding framework could no longer be added to and no new themes or details emerged. Throughout the research process the nomenclature and structure of the codes, categories and overarching categories were refined, leading to the creation of themes. CM determined themes based on her own judgements of which codes were connected in their meaning. This resulted in a complex coding framework of themes that consisted of a hierarchy of code themes, category themes and overarching category themes.

This process was overseen by LR and NB. LR, a non-clinical qualitative researcher, performed additional independent double-coding of a proportion of interview transcripts, which occurred early on in the analysis. LR and CM independently coded a proportion transcripts, then met to discuss and compare coding for the first two. LR and CM agreed that they were identifying similar overarching themes, but concluded that CM needed to code in more depth to capture more subtle details, and thereby develop the coding framework further. Following this meeting LR and CM met again to review CM's re-coding of the first five transcripts. It was determined the coding framework now contained sufficient detail for CM to continue coding independently, although the supervisory team regularly met to discuss the analysis and emerging themes throughout the research process.

2.3.9.3 Computer assisted analysis

Thematic analysis was performed in NVivo 10 software, a form of computer assisted qualitative data analysis software (CAQDAS). CAQDAS has been in use amongst qualitative communities since the 1980s and has revolutionised the lengthy process of manual coding. Researchers can store codes and retrieve the coded text easily as well as rearrange and re-name the codes to help iteratively develop a complex code framework. While the researcher continues to perform the interpretation and analysis of data, the labour involved in cutting and arranging codes has been greatly reduced. A criticism of CAQDAS is that it has the potential to transform qualitative research into a rigid automated analysis of text that in actuality requires human interpretation (98). However, given that coding is a process that is entirely based on the researcher's decision-making, the study team decided that this criticism did not warrant the abandonment of CAQDAS.

2.3.10 Assessing quality and rigor in the mixed methods qualitative research

The use of multiple methods of data collection and multiple participants has previously been described in this thesis as a means of enhancing the quality of this study through triangulation (Section 2.4.2). Other considerations include efforts to maintain a reflexive practice throughout this research and the use of multiple coders.

2.3.10.1 Reflexivity

For an approach truly founded on grounded theory the researcher should have no prior knowledge of the research topic (99, 100). That is, they should not bring their own theories and ideas into the research process. This project did not follow a true grounded theory approach, because CM had previous knowledge of the literature and background medical knowledge, which may have influenced the process of data collection and analysis. While CM had some theatre experience, it was limited, and no formal training in surgery had been undertaken. Not being surgically trained had the benefit of providing observations of surgery with fresh eyes and allowing for details that may have been ignored, or perhaps considered too obvious, to be recorded.

CM's previous medical training offered the benefit of helping her feel comfortable in theatre, and meant she had a good knowledge of safety protocols (e.g. maintaining the sterile field). Being medically trained also enabled CM to identify factors that might have implications for the surgical procedure, which could be followed up in the interviews (for example, noticing that the patient was on an immunosuppressive drug, which may affect wound healing). Medical knowledge (e.g. anatomy of the abdomen) also made the process of interviewing surgeons easier, as CM was able to broadly follow descriptions of the surgical procedure steps, and ask probing relevant questions (that were not on the topic guide) where appropriate. CM was mindful to acknowledge the impact that her medical training and mood may affect the data collection and analysis. To be considerate of this CM made additional notes during and following the mixed qualitative methods work documenting her experience during the data collection.

2.3.10.2 Multiple coding

For this research, three of the interview transcripts were double-coded by LR. This involved LR and CM cross checking the coding strategies and CM's interpretation of the data (101) . While not all of the transcripts could be double-coded due to time restrictions, having a proportion double-coded was a valuable strategy for improving the detail within the emergent coding frameworks and ensured CM remained a reflexive practice where her findings were grounded within the data.

2.4 Development of the long-list of data items

The long-list of data items is a list of all the individual overarching themes, category themes, and themes that were identified during the mixed methods qualitative research and literature review. CM approached the development of the long-list by first amalgamating the themes concerning the technical factors (the surgical variations of stoma formation) that were derived from both phases of data collection. By comparing and contrasting the themes concerning the steps and variations of stoma formation CM removed duplicates and organised the long-list of data items into a logical stepwise account of stoma formation.

This process was repeated with the non-technical factors, such as concomitant interventions, contextual factors, surgeon factors, patient factors and pre-, peri- and post-operative factors. The themes regarding the non-technical factors were again compared and arranged within their categories to create a long-list of data items.

The technical and non-technical factors were combined to create a long-list of variations that may be relevant to PSH prevention. The long-list underwent many iterations as the variations were collapsed and expanded to produce a document that was amenable to guiding discussions during a consensus meeting. This was done with input from surgeons (NB, NS and Professor Jane Blazeby). This involved discussing each data item which was reiterated until the wording became clear and more consistent. While data was reorganised and wording amended, no data was lost during this process.

2.5 Consensus meeting

The aim of the consensus meeting was to rationalise the long-list into a manageable number of data items for the case report forms.

2.5.1 Overview

Consensus methods are used to deal with scientific evidence where there is either a lack of information or information overload (102). Typically, this is performed using the Delphi Technique or a Nominal Group Technique. The Delphi Technique is a highly structured group interaction via a series of questionnaires (103). The Delphi Technique was not considered suitable for this study because it would have risked losing the theoretical construct, developed through the data collection and coding process, that underpinned the individual variations and contextual factors which the research study had identified.

Nominal Group Technique is a highly structured face-to-face group interaction (103). The Nominal Group Technique was considered too rigid (104) and too time intensive to perform. While the rigid structure of a Nominal Group Technique meeting may improve group participation, it increases the time taken to come to a decision and rejects spontaneity. The consensus process in this MSc borrowed from the Nominal Group Technique but abandoned the prescribed structure in favour of more natural discussion where each technical and non-technical factor is discussed individually, with participants contributing as much as they want to, until consensus is reached.

2.5.2 Sample

Eight surgeons from six centres were invited to participate in a structured consensus meeting. This was designed to utilise the insights of experts to enable decisions to be made. The panel was selected based on experience in stoma formation. From experience in the interviews, colorectal consultant surgeons provided the richest data and were felt to be the experts regarding stomata and PSH, therefore eight invited participants were consultant colorectal surgeons. An upper gastrointestinal surgeon and a senior colorectal registrar were also invited. Critically, we invited a Professor of Health Services Research. His input was greatly valued as he has many years of experience designing cohort studies and case report forms and provided advice on the feasibility of collecting the individual data items.

2.5.3 Recruitment

The PIs were asked to approach surgeons who would be interested in participating and to confirm their interest before they were emailed with an invite. The email addresses were acquired through the PIs following the surgeons' agreement to be contacted. If no response was received within three weeks the PIs who had recommended the individual were asked to follow these up.

The final panel consisted of seven individuals (Table 1). The long-list was distributed prior to the meeting and those unable to attend were asked to comment on the wording, structure and completeness of the long-list. Those unable to attend were not part of the consensus process and therefore did not contribute to the decision making.

Table 1: Demographics of the invited individuals for the consensus meeting

Specialty	Grade	Number invited	Number attended
Colorectal	Consultant	8	4 (three in person; one via skype)
Colorectal	Registrar	1	1
Upper Gastrointestinal	Consultant	1	1
Trialist expertise	Professor of Health Services Research	1	1

2.5.4 Gaining consensus

A chair was selected from the attendees in advance, the Chief Investigator of the CIPHER study (NS). Each data item in the long-list was discussed in turn. The chair (NS) led the discussion and invited the panellists to openly discuss if each of the data items were essential, desirable or not required for data collection in the final CIPHER CRFs. The researchers (NB and CM) also contributed to discussion by explaining the origin of the data items (e.g. if these were observed practices, reported to be an important factor by a stoma nurse during an interview, or reported in the literature). Once consensus had been reached, the next data item was discussed. This continued until the full list of data items had been discussed. Where there were discrepancies those items were highlighted by NB and CM and discussed again at the end of the meeting. Consensus was gained by the chair (NS) asking the panel for agreement and specifically asking if there were dissenters. If nobody spoke up it was considered that 'agreement/consensus' had been met. If consensus was not met then further discussion was had and if consensus could still not be met then the data item would be classified as 'desirable'.

Once all items had been categorised, the consensus meeting attendees re-discussed the 'desirable' data items, to attempt to categorise them further into 'essential' or 'not required'. Where consensus could not be met regarding further categorisation of the desirable items, the items were later discussed in a further meeting between the CIPHER study management team (including members of the CTEU, and the CI) and the research team.

2.5.5 Data collection

Written notes of decisions made in the meeting were recorded by both NB and CM onto paper copies of the long-list. The meeting was audio recorded, with consent of the attendees. Following the consensus meeting CM and NB immediately compared their written recordings to assess for discrepancies. If there were discrepancies the audio recording was reviewed to confirm the consensus decision. CM amended the long-list to create a short-list that included only the 'essential' and 'desired' data items with further amendments suggested during the consensus meeting.

2.5.6 Operationalising data items into the case report forms

The short list of data items was operationalised into case report format in conjunction with the Bristol Clinical Trials and Evaluation Unit (CTEU) team who are leading the CIPHER study. The CTEU has extensive experience in CRF design and provided valuable insights into the clarity and ordering of the data items as well as measurement units and ranges.

The final stage of CRF development was the pre-testing of the CRFs to check for understanding and usability. Senior surgeons present at the consensus meeting offered to pilot the draft CRF to their colleagues and provide feedback on format, structure and wording.

CHAPTER 3. RESULTS

This chapter presents the findings of this study.

Section 3.1 describes the findings of the literature review.

Section 3.2 presents the results of the mixed qualitative methods work.

Section 3.3 concerns the development of the long-list which was derived from both the literature review and the mixed qualitative methods work.

Section 3.4 considers the development of the short-list using consensus methods.

3.1 Literature review results

This section describes the literature review sample and the level of evidence provided by the included articles. It also briefly describes the literature review coding framework and presents the data on the technical and non-technical factors within a table.

3.1.1 Literature review sample

Six index papers were used as starting points from which to snowball from. The literature work reviewed 490 references through the process of forwards and backwards snowballing. This is demonstrated in Table 2: Snowballing process of the literature review.

Table 2: Snowballing process of the literature review

Index paper (literature starting point)	References forward snowballing	References backward snowballing	Articles excluded	Articles not located	Duplicates	Articles eligible	Additional articles included in the review (excluding duplicates)
Shabbir 2012 (55)	34	42	12	1	0	63	40
Aquina 2014 (57)	108	13	12	1	15	93	38
Hauters 2016 (105)	29	15	1	0	19	24	10
Prudhomme 2016 (106)	30	0	0	0	19	11	6
Hotouras 2013 (107)	115	42	12	6	37	102	26
Hardt 2013 (108)	52	9	4	3	29	25	6
Additional articles suggested by experts	2	0	0	0	0	0	2

Excluding duplicates 11 articles were not found, two of these were webpages that were no longer accessible. The remaining were requested through Inter Library Loans (ILLs) and were either not found in Europe or were textbooks without page specific references. Unfortunately, the purchase of the textbook references could not be funded at the time. Due to copyright laws ILLs were unable to be imported into NVivo. To resolve this the ILLs were screened and if they contained relevant text CM would copy the relevant text into a word document and import the word document into NVivo for coding.

130 articles were included in the review. A list of references can be viewed in Appendix 5. A description of the level of evidence included in the literature review can also be seen in Table 3.

Table 3: Level of evidence of the included articles in the literature review

Study type	Number of articles included in literature review
Meta-analysis	2
Randomised controlled trial	14
Systematic review	12
Prospective cohort study	20
Retrospective cohort study	35
Cross sectional study	1
Case control study	2
Case series	11
Commentary (special articles)	19
Survey	1
Randomised controlled trial protocol	3
Prospective cohort study protocol	1
Letter	3
Book chapter	3
In animal study	1
Cadaveric study	1
Laboratory study	1

3.1.2 Literature review coding framework

The literature review identified 138 technical (Table 4) and 50 non-technical factors (Table 5). These factors were derived from the coding framework that was iteratively developed using NVivo software. The coding of the included texts will not be fully discussed in this section due to word restrictions. However, section 3.4.2 provides detailed examples of how quotations from the semi-structured interviews and observations were used to create themes and contributed to the long-list of technical and non-technical factors that may be of interest to collect data on during the CIPHER study.

Table 4: Coding framework for 138 technical factors derived from the literature review.

Technical factors identified from the literature review	
Bowel preparation administered prior to surgery Y/N	
Intraoperative antibiotics given Y/N	
Surgical approach	Laparoscopic
	Open
	Trephine stoma
Type of stoma formed	End
	Loop
	Colostomy
	Ileostomy
Efforts to remove tension	Length of bowel mobilized
	Sigmoid mobilised to remove tension
Stoma pre-marked Y/N	
Stoma formed at pre-marked site Y/N	
Type of stoma formed	Trans-peritoneal
Type of stoma formed	Extra-peritoneal
Skin incision for stoma site	Size
Skin incision for stoma site	Shape
Subcutaneous adipose tissue	Divided
Subcutaneous adipose tissue	Excised
Location of the trephine	Within the rectus abdominis belly
Location of the trephine	Within the oblique abdominal muscles (lateral to the rectus abdominis)
Lateral rectus abdominis positioned stoma (LRAPS as described by Stephenson et al,.) Y/N	
Trephine location	Uncertain of relation of trephine to the rectus abdominis
Trephine location	Through a port site
Trephine location	Through the midline operative incision
Trephine location	Through a para-median operative incision
Trephine location	Through another operative incision
Trephine location	Through the umbilicus
Trephine location	Below the arcuate line
Trephine location	Above the arcuate line

Technical factors identified from the literature review	
Anterior sheath trephine	Size of anterior sheath trephine (size of widest diameter measured in cm)
Shape of anterior sheath trephine	Horizontal incision
Shape of anterior sheath trephine	Vertical incision
Shape of anterior sheath trephine	Cruciate incision
Shape of anterior sheath trephine	Circular incision
Anterior sheath trephine	Sutures to close the margins of the anterior sheath
Posterior sheath/peritoneum	Size of posterior sheath/peritoneum trephine (size of widest diameter measured in cm)
Shape of posterior sheath/peritoneum trephine	Circular incision
Shape of posterior sheath/peritoneum trephine	Cruciate incision
Shape of posterior sheath/peritoneum trephine	Horizontal incision
Shape of posterior sheath/peritoneum trephine	Vertical incision
Posterior sheath/peritoneum	Sutures to close the margins of the posterior sheath
Muscle trephine	Muscle split (separated bluntly)
Muscle trephine	Muscle incised
Muscle trephine	Muscle moved to one side (new)
Use of mechanical device to create the stoma trephine Y/N	
Use of mechanical device to create the stoma trephine	Device used on posterior sheath/peritoneum only
Use of mechanical device to create the stoma trephine	Device used on all layers of abdominal wall
Use of Alexis wound protector/retractor Y/N	
Stoma trephine manually dilated using surgeon hands Y/N	
How the measurement of the trephine was made	Finger breaths
How the measurement of the trephine was made	Anterior sheath incision measured as 50% of the 50% of the width of the patient's left colon with mesocolon measured at the point where it will pass through the fascia
Intraoperative nerve damage	Epigastric nerve injury
Intraoperative nerve damage	Lower thoracic nerve injury
Mesh use Y/N	
Mesh type	Synthetic
Synthetic	Non-absorbable
Synthetic	Polypropylene

Technical factors identified from the literature review	
Synthetic	Polyethylene terephthalate
Synthetic	Polytetrafluoroethylen (PTFE)
Synthetic	Polyvinylidene fluoride (PVDF)
Synthetic	Absorbable
Synthetic absorbable	Rapid
Synthetic absorbable	Trade name
Synthetic absorbable	Delayed (Bioabsorbable)
Synthetic absorbable	Trade name
Mesh type	Combine
Synthetic combine	Trade name
Mesh type	Biological (Brand name)
Biological	Trade name
Mesh size (cm)	
Mesh shape	2D
2D	Circle
2D	Oval
Mesh shape	3D
3D	Funnel
Location of mesh	Sublay/pre-peritoneal/retro-rectus
Location of mesh	Space created by instrument dissection
Location of mesh	Space created with blunt force (e.g. finger)
Location of mesh	Combination
Location of mesh	Underlay/intra-peritoneal
Location of mesh	Onlay
Location of mesh	Inlay
Method of positioning mesh	Through the midline or main operative incision
Method of positioning mesh	Through the stoma trephine
Mesh trephine	Sugarbaker (mesh edges secured to fascial ledges)
Mesh trephine	Modified Sugarbaker
Mesh trephine	Key-hole
key-hole	Size of key hole
Shape of key-hole	Circular
Shape of key-hole	Cruciate
Key-hole created by using a mechanical device Y/N	
Method of securing the mesh	Not secured

Technical factors identified from the literature review	
Method of securing the mesh	Tacking
Tacking mesh	Single crown
Method of securing the mesh	Suturing
Suturing the mesh	Continuous
Suturing the mesh	Interrupted at the corners of the mesh
Suturing the mesh	Interrupted
Method of securing the mesh	Combination of continuous where the mesh runs along the midline incision and interrupted
Type of sutures to secure the mesh	Absorbable
Type of sutures to secure the mesh	Non-absorbable
Method of securing the mesh	Combination of tacks and sutures
Method of securing the mesh	Use of mechanical device to secure the mesh
Method of securing the mesh	Securing the mesh to the stoma serosa
Fascial fixation/closure of the lateral space Y/N	
Fascial fixation/closure of the lateral space	Fixation of the mesentery to the abdominal wall
Fixation of the mesentery to the abdominal wall	Layer of abdominal wall sutured to
Layer of abdominal wall sutured to	Anterior sheath
Layer of abdominal wall sutured to	Posterior sheath
Layer of abdominal wall sutured to	Rectus abdominus
Layer of abdominal wall sutured to	External oblique
Method to fixate the mesentery to the abdominal wall	Sutures used Y/N
Method of suturing used to fixate the mesentery to the abdominal wall	Continuous suture
Method of suturing used to fixate the mesentery to the abdominal wall	Interrupted suture
Fixation of the stoma to the abdominal wall Y/N	
Layer of the abdominal wall sutured to	Anterior sheath
Layer of the abdominal wall sutured to	Posterior sheath
Layer of the abdominal wall sutured to	Rectus abdominus
Layer of the abdominal wall sutured to	Oblique muscles
Method to fixate the stoma to the abdominal wall	Sutures used Y/N
Method of suturing used to fixate the stoma to the abdominal wall	Continuous suture
Method of suturing used to fixate the stoma to the abdominal wall	Interrupted suture
Method of suturing used to fixate the stoma to the abdominal wall	Purse string
Trimming of stoma epiploica Y/N	

Technical factors identified from the literature review	
An assessment for stoma snugness is made by digitating the formed stoma Y/N	
Efforts made to avoid faecal spillage from the lumen of the stoma (exclude loop)	Lumen of the stoma is clamped
Efforts made to avoid faecal spillage from the lumen of the stoma (exclude loop)	Lumen of the stoma in stapled
Efforts made to avoid faecal spillage from the lumen of the stoma (exclude loop)	Lumen of the stoma is sutured
Closure of other wounds prior to creation of the stoma lumen Y/N	
Closure of additional operative sites	Sutures used
Closure of additional operative sites	Method of suturing
Efforts made to sterilise the incised stoma lumen	Swabbing incised stoma ends with anti-septic Y/N
Dressing to cover wound sites prior to creation of the stoma lumen Y/N	
Securing the stoma	Spouted (3-point suturing)
Securing the stoma	Un-spouted
Securing the stoma	Choice of sutures
Method of suturing	Purse-sting suture

Table 5: Coding framework for 50 non-technical factors derived from the literature review

Non-technical factors identified through literature review	
Post-operative prevention	Advice on a healthy lifestyle provided
Post-operative prevention	Abstinence from heavy lifting for 3 months post stoma formation
Post-operative prevention	Introduction of abdominal exercises from 3 months post stoma formation
Post-operative prevention	Introduction of abdominal exercises immediately post stoma formation
Post-operative prevention	Provision of a support garment from immediately post stoma formation
Pre-operative prevention	Weight loss
Pre-operative prevention	Smoking cessation
Pre-operative prevention	Good diabetes control
Post-operative factors	Enhanced recovery pathway
Post-operative factors	Seroma development at stoma site
Post-operative factors	Wound infection at stoma site
Post-operative factors	Post-operative sepsis
Post-operative factors	Peri-stomal abscess
Post-operative factors	Stoma stenosis
Post-operative factors	Stoma retraction
Post-operative factors	Stoma necrosis
Non-technical factors	Surgery performed as an emergency
Non-technical factors	Surgery performed electively
Non-technical factors	Grade of surgeon
Non-technical factors	Amount of blood loss during surgery
Patient factors	Gender
Patient factors	Obesity BMI >25kg/m2
Patient factors	Increased waist circumference >100cm or subcutaneous fat thickness >23mm
Patient factors	Respiratory co-morbidity
Patient factors	Other/previous abdominal wall hernia
Patient factors	Malignancy
Patient factors	Malnutrition

Non-technical factors identified through literature review	
Patient factors	Immunosuppression
Patient factors	Smoking status
Patient factors - raised intra-abdominal pressure	Chronic cough
Patient factors - raised intra-abdominal pressure	Chronic constipation
Patient factors - raised intra-abdominal pressure	Ascites
Patient factors - raised intra-abdominal pressure	Prostatic hypertrophy
Patient factors - raised intra-abdominal pressure	Obstructive uropathy
Patient factors - raised intra-abdominal pressure	Abdominal distention
Patient factors	Age
Patient factors	Diabetes
Patient factors	Corticosteroid use
Patient factors	Renal failure
Patient factors	Jaundice
Patient factors	Radiotherapy
Patient factors	Chemotherapy
Patient factors - inflammatory bowel disease	Crohns disease
Patient factors - inflammatory bowel disease	Ulcerative colitis
Patient factors	Connective tissue disorder
Patient factors	ASA anaesthetic risk
Patient factors	Previous hernia
Patient factors	Metabolic disorder
Patient factors	Oral anti-coagulant use

3.2 Mixed qualitative methods research results

This section describes the participant sample for the mixed qualitative methods research, followed by the key results of this stage of work. Three overarching themes are discussed in detail, to provide examples of how the themes were derived from the semi-structured interviews and non-participant observations. These three overarching themes were selected to be presented in the main body of the thesis because the participants considered them to be important concepts for PSH prevention. The remaining themes have been discussed in Appendix 6.

3.2.1 Interview sample

A total of 13 healthcare professionals were recruited for the semi-structured interviews from two centres: the RDE and the UHB. The semi-structured interviews were conducted by CM between 8th July 2016 and 6th October 2016. Each interview lasted between 17:22 minutes and 1:13:95 minutes and lasted on average 27:45 minutes. Interviews were conducted with three stoma nurses and ten surgeons. The surgeon speciality diversity included six lower gastrointestinal consultants, one lower gastrointestinal registrar, two upper gastrointestinal consultants and one hepatobiliary consultant. The details of each of the interview participants, including length of time in their role, and the participant identifiers used for this study, have been provided in Table 6.

Table 6: Healthcare professional semi-structured interview characteristics

Study number	Gender	Role	Length of time in role	Hospital recruited from
BRI0001	Female	Upper gastrointestinal consultant	16 years	UHB
BRI0002	Female	Stoma nurse	12 years	UHB
BRI0003	Female	Stoma nurse	3 years	UHB
BRI0004	Male	Lower gastrointestinal consultant	3 months	UHB
BRI0018	Male	Hepatobiliary consultant	10 months	UHB
BRI0009	Male	Upper gastrointestinal consultant	1 year	UHB
BRI0010	Male	Lower gastrointestinal consultant	3 years	UHB
BRI0015	Male	Lower gastrointestinal consultant	11 Years	RDE
BRI0023	Male	Lower gastrointestinal consultant	3 years	RDE
BRI0022	Male	Lower gastrointestinal registrar	7 years	RDE
BRI0032	Male	Lower gastrointestinal consultant	6 years	RDE
BRI0035	Female	Stoma nurse	5 years	RDE
BRI0036	Male	Lower gastrointestinal consultant	2 years	UHB

3.2.2 Non-participant observation sample

Six non-participant observations were performed in the two centres by CM (see Table 7 for details of the patient and operation characteristics). Digital video data capture of these operations was assisted in the RDE by Conor Jones (CJ), a Peninsular Medical School student with the appropriate theatre clearance. In the UHB the digital video data capture was assisted by Annie Skilton (AS), a member of the trust's medical imaging department.

Table 7: Non-participant observation patient sample

Patient participant study ID	Gender of patient	Date of birth of patient	Ethnicity	Type of stoma formed	Surgical approach to stoma formation	Date stoma formed	Indication for stoma formation	Planned or unplanned surgery	Hospital recruited from
BRI0014	Male	07/04/1974	White British	End colostomy	Laparoscopic	11/08/2016	Bowel management for paraplegia	Planned	RDE
BRI0021	Male	19/08/1940	White British	End colostomy	Laparoscopic	19/08/2016	Bowel management for multiple sclerosis	Planned	RDE
BRI0030	Female	16/05/1971	White British	End colostomy	Open	01/09/2016	Bowel cancer	Planned	UHB
BRI0033	Female	08/12/1984	White British	End Ileostomy	Laparoscopic	23/09/2016	Inflammatory Bowel Disease	Planned	RDE
BRI0034	Male	07/06/1962	White British	End Ileostomy	Converted laparoscopic to open	06/10/2016	Bowel cancer	Planned	UHB
BRI0037	Male	14/03/1932	White British	End colostomy	Open	29/10/2016	Sigmoid volvulus	Unplanned	UHB

3.2.3 Technical and non-technical variables identified through mixed qualitative methods

The mixed qualitative methods work resulted in 150 technical (Table 8) and 64 non-technical factors (Table 9) that had potential to influence the development of PSH, 77 of these were not identified in the literature. While many technical and non-technical variables in stoma surgery were identified, it was not always clear how important the participants felt that each of these were, in terms of their influence on risk of PSH formation. Participants often mentioned a factor/variable but did not elaborate on how they felt it would impact on PSH rates, or in some cases, they felt unable to comment on their significance. In these cases, the variables were still included in the results, as it was felt to be important to still present these findings for further discussion in the consensus meeting.

Table 8: The 150 technical factors identified through mixed qualitative methods research

Technical factors identified through mixed-methods qualitative research	
Surgical approach	Laparoscopic
Surgical approach	Open
Surgical approach	Mixed
Surgical approach	Trephine stoma
Type of stoma formed	End
Type of stoma formed	Loop
Type of stoma formed	Double barrel
Type of stoma formed	Colostomy
Type of stoma formed	Ileostomy
Type of stoma formed	Transverse colostomy
Type of stoma formed	Temporary
Type of stoma formed	Permanent
Type of stoma formed	Conversion of loop to end
Length of bowel mobilised (cm)	
Mobility of bowel	Stoma formed under tension
Mobility of bowel	Bowel excessively mobile
Pre-marked stoma site Y/N	
Steps taken to maintain stoma marking Y/N	
Steps taken to maintain stoma marking	Arrows pointing at marked stoma site
Steps taken to maintain stoma marking	Sutures placed at marked stoma site
Multiple marked stoma sites Y/N	
Stoma formed at a pre-marked site Y/N	
Skin is surgically prepped Y/N	
Route of stoma	Transperitoneal
Route of stoma	Extra-peritoneal
Route of stoma	Oblique
Efforts made to align abdominal wall layers during an open procedure	
Methods of creating skin incision	Scalpel
Methods of creating skin incision	Diathermy
Size of skin incision (cm)	
Shape of skin incision	Circular
Shape of skin incision	Oval
Further adjustments to shape to create symmetry of skin incision Y/N	
Haemostasis achieved for skin incision Y/N	

Technical factors identified through mixed-methods qualitative research	
Subcutaneous adipose	Divided
Subcutaneous adipose	Excised
Subcutaneous adipose	Column (core) shape excised – similar diameter of adipose excised down to the anterior sheath
Subcutaneous adipose	Cone shape excised
Location of the trephine	Within the rectus abdominis belly
Location of the trephine	Within the oblique muscles
Location of the trephine	Lateral rectus abdominis positioned stoma (LRAPS as described by Stephenson et al,.) Y/N
Location of the trephine	Uncertain of relation of trephine to the rectus abdominis
Location of the trephine	Through the operative incision
Location of the trephine	Through the umbilicus
Location of the trephine	Through a port site
Location of the trephine	Below the arcuate line
Location of the trephine	Above the arcuate line
Location of the trephine	Disruption of the linear semilunaris
Location of the trephine	Location of trephine in relation to current or previous operative sites
Size of anterior sheath trephine (size of widest diameter measured in cm)	
Shape of anterior sheath trephine	Circular incision
Shape of anterior sheath trephine	Cruciate incision
Shape of anterior sheath trephine	Horizontal incision
Shape of anterior sheath trephine	Vertical incision
Buttressing the ends of the incision on the anterior sheath Y/N	
Size of posterior sheath incision (cm)	
Shape of posterior sheath/peritoneum trephine	Circular incision
Shape of posterior sheath/peritoneum trephine	Cruciate incision
Shape of posterior sheath/peritoneum trephine	Horizontal incision
Shape of posterior sheath/peritoneum trephine	Vertical incision
Shape of posterior sheath/peritoneum trephine	Punctured with blunt force (e.g. using a trocar)
Use of assistant to provide retraction while making the stoma trephine Y/N	
Muscle trephine	Muscle incised
Muscle trephine	Muscle split
Was the trephine enlarged Y/N	
Enlarging the trephine	Blunt force
Enlarging the trephine	Incision
Enlarging the trephine with an incision	Diathermy

Technical factors identified through mixed-methods qualitative research	
Enlarging the trephine with an incision	Scalpel
Enlarging the trephine with an incision	Scissors
Enlarging the trephine	Accidental tearing of the sheath or muscle during retraction or dilatation
Further sutures at margins of anterior sheath to narrow the trephine Y/N	
How the measurement of the trephine was made	Finger breaths
How the measurement of the trephine was made	By eye
How the measurement of the trephine was made	Combination of eye and finger breaths
laparoscopic procedure - level of inflation during trephine formation	Ensure deflation of the abdomen during trephine formation
laparoscopic procedure - level of inflation during trephine formation	*A*bdomen inflated during trephine formation
Laparoscopic procedure - use of stoma trephine as an extraction site Y/N	
laparoscopic procedure - use of stoma trephine as an extraction site	Large bowel specimen
laparoscopic procedure - use of stoma trephine as an extraction site	Small bowel specimen
laparoscopic procedure - use of stoma trephine as an extraction site	Purposeful widening the trephine for use as an extraction site by manually dilating the trephine
laparoscopic procedure - use of stoma trephine as an extraction site	Purposeful widening the trephine for use as an extraction site by incising the trephine
laparoscopic procedure - use of stoma trephine as an extraction site	Attempts made to close the widened trephine if widened by incision or tear
Laparoscopic procedure - Use of the stoma trephine as a port site (without requiring further adjuvants to create an air seal e.g. alexis wound protector and glove) Y/N	
laparoscopic procedure - Use of the stoma trephine as a port site	Widening of the stoma trephine after removing the port
Mesh used Y/N	
Mesh type	Biologic
Biologic mesh	Brand
Mesh type	Synthetic
Synthetic mesh type	Brand
Mesh type	Mesh contains antibiotics
Mesh size (Cm)	
Mesh size	Mesh cut to a size other than size manufactured
Mesh shape	Oval
Mesh shape	Circle
Mesh shape	Rectangle
Mesh shape	Square
Location of mesh	Sublay, pre-peritoneal, retro-rectus

Technical factors identified through mixed-methods qualitative research	
Location sublay, pre-peritoneal, retro-rectus	Space created by instrument dissection
Location sublay, pre-peritoneal, retro-rectus	Space created with blunt force (e.g. finger)
Location sublay, pre-peritoneal, retro-rectus	Combination
Location of mesh	Underlay, intra-peritoneal
Location of mesh	Onlay
Location of mesh	Inlay
Mesh trephine	Sugarbaker (mesh edges secured to fascial ledges)
Mesh trephine	Modified Sugarbaker
Mesh trephine	Sandwich (as described by Dieter Berg)
Mesh trephine	Key-hole
Key hole size (cm)	
Shape of key hole	Circular
Shape of key hole	Cruciate
Shape of key hole	Made after the mesh has been secured
Method of positioning the mesh	Through the midline incision or main operative incision
Method of positioning the mesh	Through the stoma trephine
Method of securing the mesh	Not secured
Method of securing the mesh	Tacking
Tacking to secure the mesh	Single crown
Tacking to secure the mesh	Double crown
Method of securing the mesh	Suturing
Suturing the mesh - method of suturing	Continuous
Suturing the mesh - method of suturing	Interrupted
Bowel delivered through the stoma trephine Y/N	
Delivering the bowel through the stoma trephine	Checking the orientation of bowel being bought out
Delivering the bowel through the stoma trephine	Replacing the omentum over remaining bowel
Delivering the bowel through the stoma trephine	Gas off when delivering the bowel out
Assessment of trephine stoma snugness made Y/N	
Use of wound protector/retractor (E.g. Alexis) Y/N	
Squeezing the bowel to reduce oedema during bowel delivery Y/N	
Widening the trephine Y/N	
Widening the trephine	Incision
Widening the trephine	Tearing
Widening the trephine	Additional sutures to narrow the trephine following widening
Fascial fixation Y/N	

Technical factors identified through mixed-methods qualitative research	
Fascial fixation	Tacking or suturing the bowel to the fascia
Fascial fixation	Tacking or suturing the bowel to the muscle
Mesentery stripped Y/N	
Mesentery stripping	Trimming of epiploic fat
Mesentery stripping	Trimming of the mesentery of the stoma
Closure of other wounds prior to creation of the stoma lumen Y/N	
Laparotomy closure Y/N	
Closure of laparotomy site	Deep layer small bite closure
Closure of laparotomy site	Deep layer large bite closure
Use of glue to cover wound sites prior to creation of the stoma lumen Y/N	
Cleaning the abdomen prior to creation of the stoma lumen Y/N	
Securing the stoma	Spouted
Securing the stoma	Un-spouted
Securing the stoma	Subcuticular bite of skin
Securing the stoma	Full thickness bite of skin
Securing the stoma	No gaps or subcuticular fat protruding from muco-cutaneous junction
Local anaesthetic applied around the stoma site	

Table 9: The 64 non-technical factors identified through mixed-methods qualitative research

Non-technical factors identified through mixed-methods qualitative research	
Patient factors	Known or previous abdominal aortic aneurysm
Patient factors	Age
Patient factors	Cardiovascular disease
Patient factors	Inflammatory state
Patient factors	Chemotherapy
Patient factors	Chronic cough
Patient factors	Concomitant incisional hernia
Patient factors	Connective tissue disorder
Patient factors	Diabetes
Patient factors	Distended abdomen at the time of surgery
Patient factors	Diverticular disease
Patient factors	Heavy lifting
Patient factors	Inflammatory bowel disease
Patient factors	Immunocompromised state
Patient factors	Intra-abdominal infection
Patient factors	Lung disease
Patient factors	Malignancy
Patient factors	Nutritional status
Patient factors	Obesity
Patient factors	Obstructive symptoms
Patient factors	Oedematous or dilated bowel
Patient factors	Post-partum female
Patient factors	Previous abdominal surgery
Patient factors	Previous abdominal surgery affecting choice of stoma location
Patient factors	Previous hernia
Patient factors	Radiotherapy
Patient factors	Renal failure
Patient factors	Sepsis
Patient factors	Smoking
Patient factors	Steroid use
Patient factors	Weak abdominal muscles
Non-technical surgical factors	Pre-operative stoma therapist consultation
Non-technical surgical factors	Stoma formation performed as an emergency
Non-technical surgical factors	Stoma formation performed as an elective procedure
Non-technical surgical factors	Time of day surgery performed
Non-technical surgical factors	Specialty of the stoma forming surgeon
Non-technical surgical factors	Competency of the surgeon
Non-technical surgical factors	Grade of the surgeon
Non-technical surgical factors	Level of supervision if consultant not performing the stoma formation

Non-technical factors identified through mixed-methods qualitative research	
Level of supervision if consultant not performing the stoma formation	Scrubbed assisting
Level of supervision if consultant not performing the stoma formation	Scrubbed observing
Level of supervision if consultant not performing the stoma formation	Un-scrubbed direct observing
Level of supervision if consultant not performing the stoma formation	Un-scrubbed in the room
Level of supervision if consultant not performing the stoma formation	Un-scrubbed not observing
Post-operative factors	Admission to HDU or ITU
Post-operative factors	Enhanced recovery pathway
Post-operative factors	Post-operative cough
Post-operative factors	Post-operative complications Y/N
Post-operative complications	Ischemic stoma
Post-operative complications	Stoma infection
Post-operative complications	Retracted stoma
Post-operative complications	Post-operative chest infection
Post-operative complications	Post-operative sepsis
Post-operative complications	Raised intra-abdominal pressure post-operatively
Post-operative complications	Reoperation
Pre-operative prevention	Antibiotics given intra or pre-operatively
Pre-operative prevention	Exercise programme
Pre-operative prevention	Smoking cessation
Pre-operative prevention	Weight loss
Post-operative prevention	Return to exercise too quickly
Post-operative prevention	Wearing protective corset/belt
Post-operative prevention	Post-operative cough protection advice from the stoma nurses
Post-operative prevention	Avoiding heavy lifting for 3 months
Post-operative prevention	Early engagement in abdominal muscles

3.2.4 Presentation of the data

The data have been divided into 'technical' and 'non-technical' factors. Three overarching themes derived from the mixed qualitative methods work are presented below. These include two technical factors ('the location of the stoma trephine', and 'the use of mesh'); and one non-technical factor ('patient factors'). Verbatim quotations from interview participants and CM's and NB's notes from the non-participant observations have been selected to illustrate how the themes were derived. Participant identifiers have been included in brackets beneath the quotations from the healthcare professional interviews. To demonstrate the breadth of opinions, participant identifiers include the healthcare professional's specialty and level of training. For quotations derived from the non-participant observation and digital video data capture, contextual detail such as the type of operation being observed have been recorded in brackets beneath the cited observation notes. Figure 6 and Figure 7 provide examples. In most cases, the technical and non-technical factors were explored in relation to perceived impact on risk of PSH, but there were occasions where practices could not be explored in relation to PSH due to the natural flow and time constraints of the interviews. Where informants discussed implications for PSH, this has been reported. In some of the verbatim quotations, supplementary text surrounded by brackets (e.g. [text]) have been added where further explanation or context is needed for the reader to make sense of the quotation.

HCP: [BRI0001, Surgeon, Upper GI, UHB]

The unique study code for that participant	Type of HCP (Surgeon or stoma nurse)	Specialty if the HCP is a surgeon	Location recruited from

Figure 6: Example of participant identifier for the semi-structured interview quotations

Observation CM: [BRI0014, End colostomy, Laparoscopic, UHB]

The unique study code for that participant	Type of stoma formed	Surgical approach	Location recruited from

Figure 7: Example of participant identifier for CM or NB observation quotations

3.2.5 Technical factors

The term 'technical' factors has been used to encompass all factors relating to the surgical techniques or choices made by the surgeon within the operation. From the data, it was clear that the participants strongly felt that technical factors contributed to risk of PSH development. However, there was uncertainty or a lack of specificity about which technical factors were most important to PSH prevention, as demonstrated by the quotes below:

> *"I think good surgery must be the answer, but I'm not sure what the technique is (Laughter)."* [HCP: BRI0001, Surgeon, Upper GI, UHB]

> *"If I'm going to put my money on one thing, the thing I'm going to put my money most on is poor technique."* [HCP: BRI0015, Surgeon Lower GI, RDE]

Furthermore, while the surgeons had strong views about technical variations, the stoma nurses felt that they did not have enough experience with the technical aspects of stoma formation to comment considerably on the technical aspects:

> *"There could be (a difference in surgeon skill), but that's quite difficult for me to comment on, because I'm never in surgery and I don't really know… Because I'm not in theatre, because I don't really know and I don't write down the technique."* [HCP: BRI0003, Stoma Nurse, UHB]

The following two sections (3.4.2.1 and 3.4.2.2) will discuss two of the identified overarching themes that fell within the 'technical factors' category: 'location of the stoma trephine', and 'use of mesh'.

3.2.5.1 Location of the stoma trephine

Semi-structured interview respondents used the term ‘trephine’ to describe the hole or opening in the abdominal wall for the stoma to pass through (Figure 8).

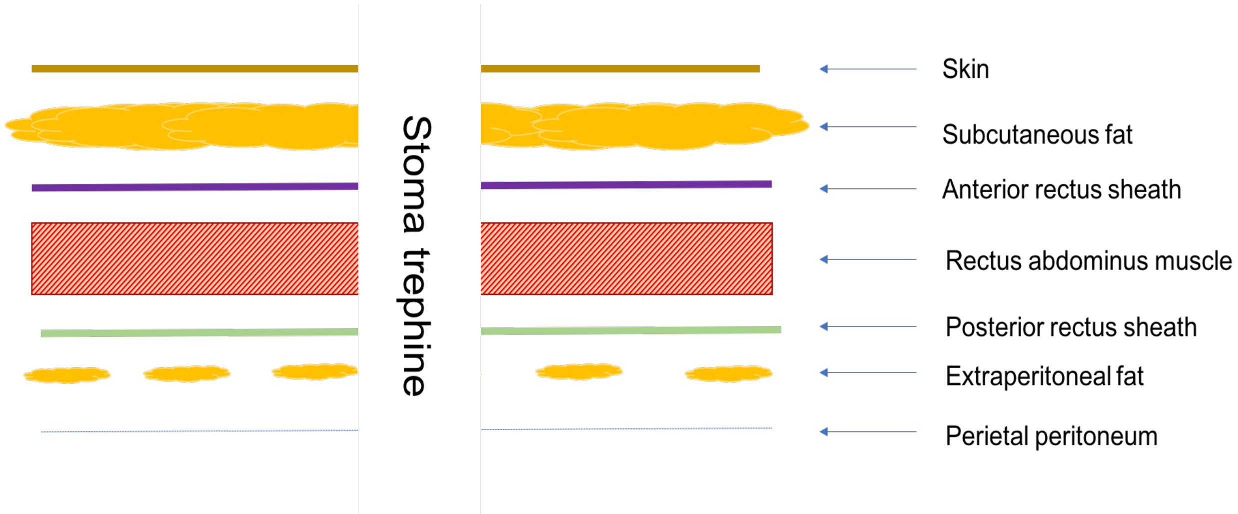

Figure 8: Image displaying a stoma trephine through the layers of the anterior abdominal wall at the level of the rectus sheath above the arcuate line

A trephine has been defined in the literature as a cylindrical-shaped core of skin and subcutaneous fat that is removed from the pre-marked stoma site, through which the stoma is brought to the skin surface (109). Most surgeon participants felt that the location of the stoma trephine was important for PSH prevention. Figure 9 demonstrates the different layers of the abdominal wall that a stoma trephine may be created through.

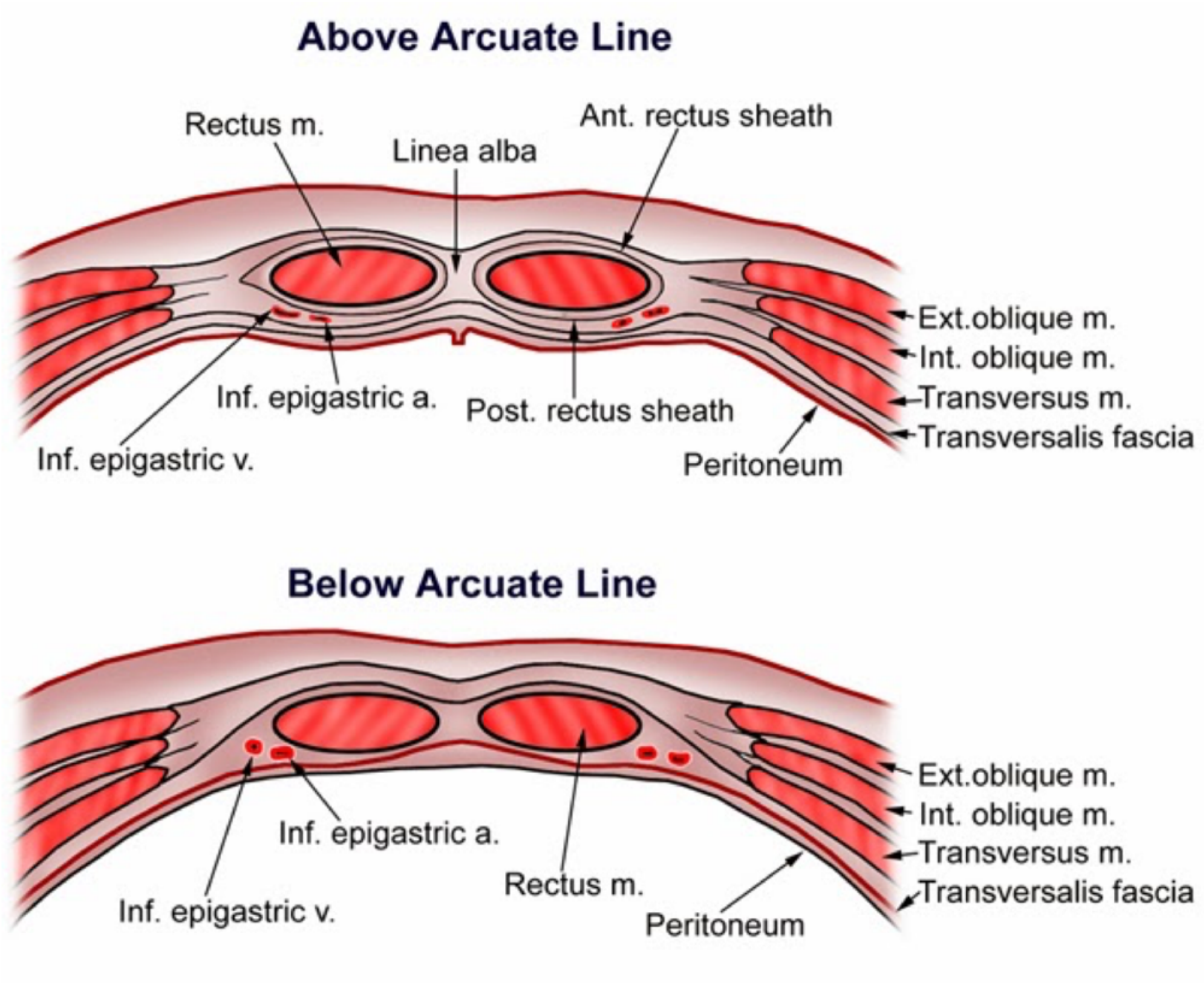

Figure 9: Constituent layers of the abdominal way above and below the arcuate line

There are many locations in which a stoma trephine may be formed, as shown in Figure 10. The stoma can be formed: i) in the midline (or “linea alba”) (red route), ii) within the belly of the rectus abdominus (green), iii) lateral to the belly of the rectus abdominus (purple), or iv) lateral to the rectus abdominus, by either disrupting the semilunaris (yellow) or lie within the oblique muscles (blue). It can also be formed within all of these locations above and below the arcuate line. The arcuate line is an anatomical description that demarcates the lower limit of the posterior layer of the rectus sheath Figure 11). The surgeons commonly referred to the rectus sheath as an anatomical description. The rectus sheath contains the rectus abdominus muscle and can be divided into the posterior and anterior rectus sheath. It is created by the aponeuroses (fibrous tissue) of the tranversus muscles and the external and internal oblique muscles (110).

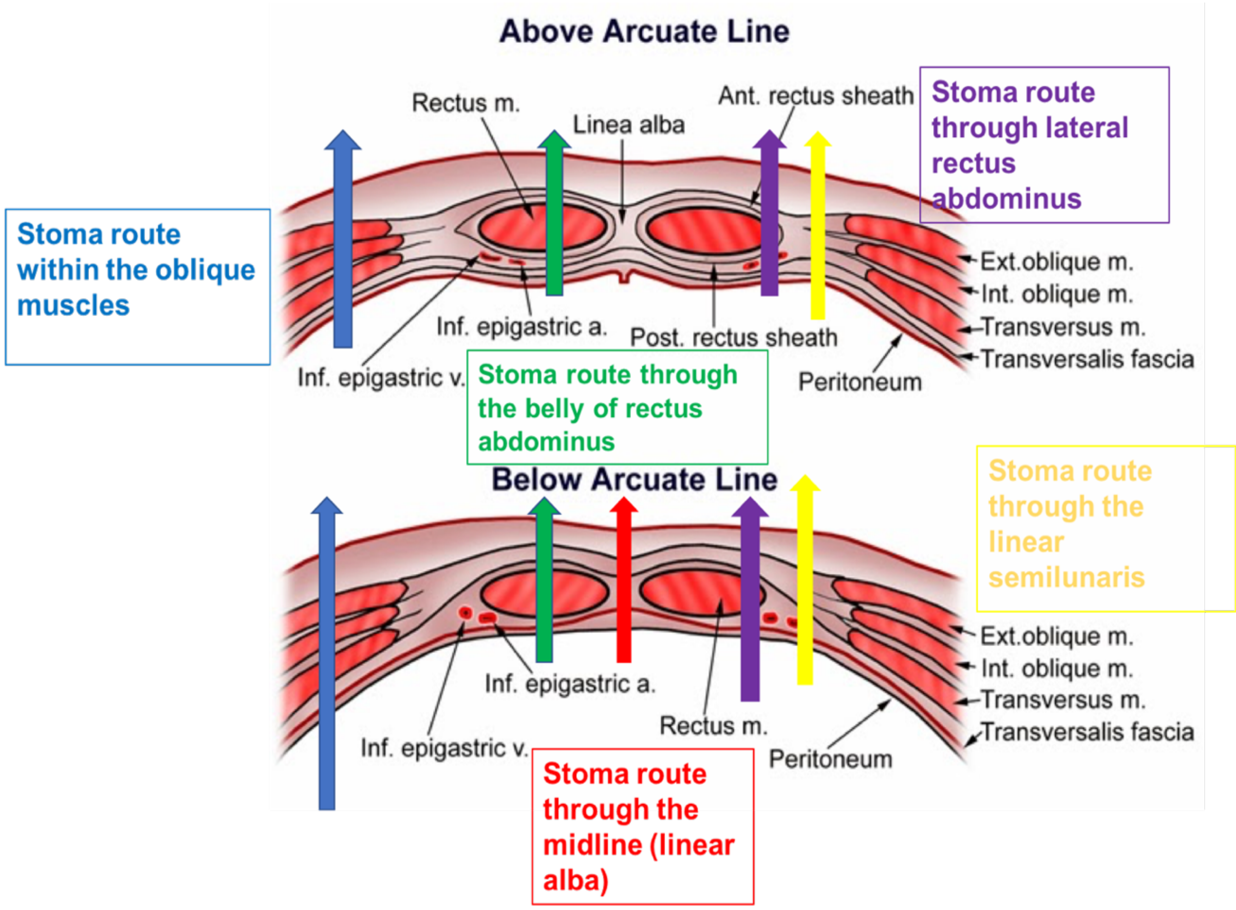

Figure 10: Possible routes for a stoma trephine above and below the arcuate line

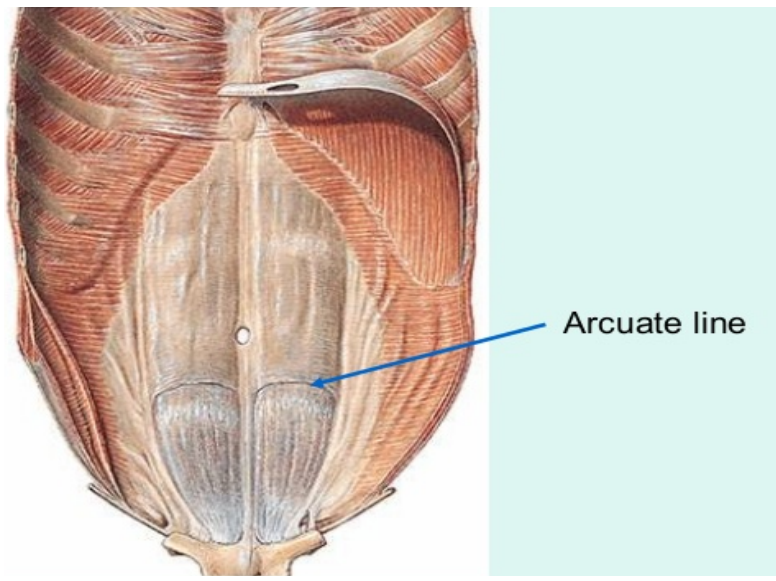

Figure 11: Image depicting the location of the arcuate line

Stoma placement through the rectus abdominus muscle or the oblique muscles

All surgeons reported placing the stoma trephine through the rectus abdominis (the green route in Figure 10). All of the stoma nurses and most of surgeons felt that the stoma trephine would be protected from widening by placing the stoma trephine within the rectus sheath because of the triple layer of abdominal wall or greater muscle bulk that exists in the rectus sheath. The surgeons hypothesised that the rectus sheath would "reinforce" and protect the trephine from widening. This was deemed important because a widened trephine was thought to create space that the bowel could move into (i.e. thus leading to a PSH):

> *"I think it makes a difference. If you put the trephine within the rectus sheath then the rectus sheath is a closed compartment because you've got a posterior and anterior layer and lateral and medial. Therefore any rise in the force or the pressure within that rectus abdominal muscle by the passage of stoma, or material through a stoma, is equalised by the fact it's a closed compartment so you get are resistant force. If you put it outside the rectus abdominus, in the obliques, then by the very nature of which your obliques and transverse salus separate then they're more likely to separate around a stoma. I think there's a difference in whether the patient's got a posterior sheath or whether you've got a peritoneum because if you've only got a peritoneum you're less likely to have a resisted force because it's dissipated by the peritoneum at the back as opposed to posterior sheath."* [HCP: BRI0015, Surgeon, Lower GI, RDE]

Interviewer: "Do you think that will make a difference if you did that in the external oblique?"

Respondent: "Yes, because there is more muscle bulk and tissue where the rectus abdominis is compared to the external oblique." [HCP: BRI0022, Surgeon, Lower GI, RDE]

Seven surgeons felt it was important to place the trephine through the rectus, one individual went further by specify that PSH rates could be influenced depending on whether the stoma trephine was placed through the 'belly' (green route in Figure 10) of the rectus or through the 'lateral' rectus, a technique published by Stephenson et al (purple route in Figure 10) (111):

"I don't do the lateral rectus, I do through the rectus. The lateral rectus was described by Gethin Williams and Brian Stephenson of the Newport published in Colorectal Disease." [HCP: BRI0015, Surgeon, Lower GI, RDE]

Although a number of surgeons expressed views about the trephine location being important, there were also a few surgeons who explained that while they would place the stoma trephine within the rectus there were elements of uncertainty of the protective importance of this factor:

"I honestly don't know. You could imagine it might [make a difference in PSH rates], but I don't know." [HCP: BRI0018, Surgeon, Hepatobillary, RDE]

"I'm a general surgeon, not a colorectal surgeon – I would place the trephine, I don't know, probably inside the rectus sheath. Is it supposed to be inside or outside?... The thing I'm not sure whether it's right or wrong

is whether you do it in the rectus sheath or extra rectus sheath" [HCP: BRI0001, Surgeon, Upper GI, UHB]

"I've been previously taught that if it went through the rectus sheath and was surrounded by the muscle, that's theoretically supposed to reduce the risk of parastomal hernias. But they still happen". [HCP: BRI0009, Surgeon, Upper GI, UHB]

Interviewer: "And if it was outside of the rectus do you think that would make a difference to parastomal hernia rates?"

Respondent: "Hhhhhh no not necessarily, I don't, I don't think it's an important thing I mean feasibly yes but I don't think it's as important as other factors." [HCP: BRI0036, Surgeon, Lower GI, UHB]

Placing the stoma above or below the arcuate line

Two surgeons noted that the location of the trephine in relation to the arcuate line may be important in PSH prevention, with trephines located above the arcuate line being less likely to result in PSH. This was theorised to be because the posterior sheath ceases to exist below the arcuate line and that the posterior sheath may provide additional reinforcement to prevent the trephine from widening. Figure 10 demonstrates the lack of posterior rectus sheath below the arcuate line and Figure 11 displays the location of the arcuate line.

Respondent: "The arcuate line of Douglas may well be important. Those which are situated below it, you may find that there are more problems."

Interviewer: "Is that because of the presence of a posterior sheath?"
Respondent: "And that patients who have above the arcuate line of

Douglas may be less inclined to have parastomal hernias." [HCP: BRI0023, Lower GI, RDE]

Disrupting the linear semilunaris

Other factors noted by surgeons to negatively impact on outcomes included whether or not the trephine was located in the linea semilunaris (yellow route in Figure 10, as well as the close proximity of the stoma trephine to other surgical scars or incisions. Although the surgeons discussed these as practices to avoid, it was not clear if they believed these factors increase the risk of PSH development.

> *"Disrupting the linea semilunaris I think is a recipe for disaster."* [HCP: BRI0023, Lower GI, RDE]

> *"The other thing you've got to remember is if you've got a wound to close and where I've seen people run into trouble is if you create a very medial stoma you don't then have much fascia with which to close your abdominal wound and they could quite easily get a degree of dehiscence in the abdominal wound or, and/or parastomal hernia, I suppose it could drag open the, the stoma hole."* [HCP: BRI0036, Surgeon, Lower GI, UHB]

> *Interviewer: "I was wondering about location of the trephine in terms of previous operations [scars] as well."*
>
> *Respondent: "Well this goes back to one of the theories about inguinal hernias are more common on the right than the left, is that because people have had appendices out?" [appendix surgical scars are always right-sided]* [HCP: BRI0032, Surgeon Lower GI, RDE]

Other variations of stoma placement

Two additional variations in stoma placement were discussed during the semi-structured interviews. These were forming a stoma through the midline incision and placing the stoma trephine through the umbilicus. Though the surgeons discussed these negatively, their reasoning for believing that these variations would increase the risk of PSH development was not fully explored by CM.

A further variation that was observed during the non-participant observation was that the surgeon may place the stoma trephine through a site initially used as a port site.

> *"There is a small incision in the RUQ which looks a bit like a port site…The surgeon picks up one edge of the (port site) incision and uses the diathermy to extend it horizontally. Two small vertical extensions are also made with the diathermy. The incision is now a cruciate shape... The surgeon puts a Babcock through the stoma incision and grasps the small bowel. The loop of bowel is then brought out through the stoma site."* [Observation NB: BRI0034, End Ileostomy, Converted laparoscopic to open, UHB]

> *"I would definitely keep it out of the midline."* [HCP: BRI0009, Surgeon, Upper GI, UHB]

> *"There's something called Single Incision Laparoscopic Surgery – SILS – where everything is done through a tiny little umbilical wound."* [HCP: BRI0018, Surgeon, Hepatobiliary, RDE]

3.2.5.2 Use of mesh

The interviews and observations showed that surgeons may or may not choose to use mesh when creating a stoma. Mesh is a sheet of woven material that may be implanted during surgery to provide support to organs or tissues (112). There were many variations identified relating to the use of mesh, including what type of mesh to use, where to place the mesh and how to pass the stoma through the mesh. There were also differences in opinion about the implications on PSH development.

Use of mesh to reinforce the stoma site

The use of mesh to reinforce the stoma site at the primary stoma formation has been proposed as a PSH preventative method in the literature (113). This was theorised by some of the interviewed surgeons to strengthen the abdominal wall where an incision has been made for the stoma to pass through. They felt that the mesh may create 'support', 'control' or a 'barrier' for PSH prevention.

> *Interviewer: "How do they develop parastomal hernias?"*
>
> *Respondent: "I think what causes that, in my view, is because you're bringing the bowel through the muscles, you're already creating a defect, you're already creating a hernia. With time, the muscle tone goes less around that defect and then they start developing a hernia or if they're overweight, the fat content, again, doesn't help with the parastomal hernia formation. The mesh prevents that because with mesh you have a little bit of control."* [HCP: BRI0010, Lower GI, UHB]

> *"Why does it work? In theory, I think, is that because of the tissue ingrowth that occurs into it you get a scar, which then means the trephine*

hole is more resistant to the forces that act upon it, which encourage it to increase in its diameter, so you have something which is more fixed in size…Therefore, it acts as a barrier when the intra-abdominal contents are trying to push through. It's usually the point between the trephine and where the bowel comes through the trephine, which is where pressure is exerted by the intra-abdominal contents and forces everything open." [HCP: BRI0023, Lower GI, RDE]

"Because essentially what you're doing with prophylactic mesh is replicating the strength of the anterior sheath on the posterior sheath, so that you can provide a stabilisation, if you like, of the trephine hole that you've made.' [HCP: BRI0023, Lower GI, RDE]

Some surgeons strongly felt that mesh had a preventative role in PSH development and were actively using mesh in their clinical practice as demonstrated by two of the non-participant observations where surgeons were observed using mesh:

"The consultant then places the mesh with the retrorectus space. Using a curved needle the mesh is sutured in the lower right corner to the posterior sheath and tied by the consultant" [Observation CM: BRI0030, End Colostomy, Open, UHB]

"Heiss used to insert mesh into retro-rectus space, maneuvered with consultants index finger". [Observation CM: BRI0021, End Colostomy, Laparoscopic, RDE]

Three surgeons (BRI0001, BRI0009 and BRI0018) reported not ever using mesh when they create a stoma. One surgeon reported that this was because the evidence surrounding the use of mesh was inconclusive. There was also a suggestion that the evidence on the use of mesh was perhaps not well known amongst all of the surgeons.

> *Interviewer: "Do you ever use a mesh at all?"*
>
> *Respondent: "Not when I've formed one in the beginning, no…I don't have enough experience or know the literature to really tell you."* [HCP: BRI0018, Surgeon, Hepatobiliary, RDE]

Some surgeons felt that there was a role for mesh in PSH prevention though they did not use it universally in all of their stoma formations because of risks and other considerations such as the intended longevity of the stoma. If a surgeon did not routinely use mesh to reinforce the stoma, there were still some scenarios where they felt mesh might be introduced (e.g. if creating a permanent ostomy, or if the patient has had a PSH at another stoma site in the past). These decisions appeared to be based on anecdotal experience, and the surgeon weighing the risks and benefits of mesh use:

> *"If the patient is going to get a permanent end colostomy, because they're having abdominoperineal excision, for example, I would use in most patients a piece of polypropylene mesh in the retrorectus position"* [HCP: BRI0023, Lower GI, RDE]

> *Interviewer: "What are the factors that make you more inclined to put a mesh in?"*
>
> *Respondent: "If the patient's got no infection. So if the patient's already got a stoma I wouldn't put a mesh in because I've got a contaminated field; unless I'm reconstructing them, a parastomal [hernia repair] in which case I use a biologic mesh. I'll use a synthetic mesh in somebody I'm*

creating a stoma for the first time where there's no open bowel involved in the operation" [HCP: BRI0015, Lower GI, RDE]

"If the patient is going to get a permanent end colostomy, because they're having abdominoperineal excision, for example, I would use in most patients a piece of polypropylene mesh in the retrorectus position… For ileostomies, the difference is that as they're designed to be temporary, if I was doing a temporary defunctioning loop ileostomy, I would not use prophylactic mesh…In an emergency situation, where the patient has, for example, something like a Hartmann's procedure, I tend not to use prophylactic mesh…So upfront they get a permanent end colostomy formed, with the distal end stapled off and left inside, and they get the prophylactic mesh upfront." [HCP: BRI0023, Lower GI, RDE]

Overall, there was diversity and sometimes polar opinions regarding use of mesh, as illustrated in Table 10. Consequently, in practice, it appeared that the use of mesh when creating a stoma was a surgeon specific decision.

Table 10: Opinions on the use of prophylactic mesh to prevent PSH. Table highlighting the polarity of views on the use of mesh to prevent a PSH

For the use of mesh	*"I put an intraperitoneal mesh to stop the parastomal hernia. That is my anecdotal experience, I've done 10 or 15 of those and I think they are less likely to get hernias, but even if they get hernias, they're less likely to be symptomatic."* [HCP: BRI0010, Lower GI, UHB]
	"If the patient is going to get a permanent end colostomy, because they're having abdominoperineal excision, for example, I would use in most patients a piece of polypropylene mesh… It's why most of the RCTs would demonstrate nowadays a protective effect with prophylactic mesh." [HCP: BRI0023, Lower GI, RDE]
Against the use of mesh	*"See, the fact that all these different meshes are being used for parastomal hernias must mean that no one of them is actually working. The more ways there are of doing something, the more sure you are that nobody knows what the right way is."* [HCP: BRI0009, Upper GI, UHB]
Doesn't use mesh due to the uncertain of the evidence	*"I don't use mesh to try and reinforce the stoma; I've never… I'm not aware of the evidence. I know there are trials ongoing at the moment; there are a few trials, but I'm not sure if any of them are well designed and conducted."* [HCP: BRI0001, Surgeon, Upper GI, UHB]

	"Yes, I've read about electively placing mesh around the site of a parastomal hernia. But anecdotally when I've spoken to co-directional surgical colleagues, they've kind of said, "Well, the evidence for the- their routine use is poor." And I haven't really defined in my own mind if there is a patient group that will definitely benefit from an elective mesh replacement at the time of the stoma". [HCP: BRI0009, Surgeon, Upper GI, UHB]
Believes mesh should only be used in research scenarios due to evidence uncertainty	*"Mesh is a contentious issue at the moment about whether we use it or not. At the moment it should really only be used in a trial scenario, it is not standard procedure at the moment."* [HCP: BR0022, Surgeon, RDE]
	"If I'm putting mesh in because Mr X has asked me to put mesh in for a study... Well some people we put mesh in, some people we don't." [HCP: BRI0015, Lower GI, RDE]
Decision to use mesh or not depends on the context of the surgery	*Interviewer: "What are the factors that make you more inclined to put a mesh in?"* *Respondent: "If the patient's got no infection. So if the patient's already got a stoma I wouldn't put a mesh in because I've got a contaminated field; unless I'm reconstructing them, a parastomal [hernia repair] in which case I use a biologic mesh. I'll use a synthetic mesh in somebody I'm creating a stoma for the first time where there's no open bowel involved in the operation"* [HCP: BRI0015, Lower GI, RDE]
	Interviewer: "Do you use mesh to re-enforce your stomas ever?" *Respondent: "Uh I've done it in someone who has had a parasto-, if they've had previous stomas, previous hernias I might consider doing it um I've done it a few times, once I've lived to regret it because they then had a poorly functioning stoma but I've done it a few times with reasonable effect. So I have had done it but in people who seem to have a previous position to parastomal hernias or have had them before but I don't routinely do it."* [HCP: BRI0036, Surgeon, Lower GI, UHB]

Surgeons also commented on the risks associated with the use of mesh (e.g. erosion of the bowel):

> *"Would I feel comfortable about putting a synthetic mesh around the bowel? Probably not… simply because of the risk of erosion but I have no evidence to back that up, that's just the gut feeling, so to speak".* [HCP: BRI0004, Lower GI, UHB]

> *Interviewer: "So you get erosions?"*
>
> *Respondent: "Erosion, fistulation, etc., and how you've attached that mesh, particularly if you do intraperitoneal placement, either as a keyhole or as a Sugarbaker type procedure, the fixation that you use comes with its own consequences".* [HCP: BRI0023, Lower GI, RDE]

> *"I've seen meshes eroding through the bowel, so I'm reluctant to use it."* [HCP: BRI0010, Lower GI, UHB]

Some surgeons perceived the use of mesh to only be a short-term solution to PSH prevention, due to the phenomenon of 'mesh shrinkage', where the edges of the mesh would shrink, thus widening the trephine and creating space for bowel to move into:

> *"The honest answer is I'm not certain whether mesh prevents parastomal hernias or not, or whether it merely delays the inevitable. If it's a delay to the inevitable that may well be worthwhile having anyway, to have patients symptom free for longer periods of time... The downside is that over time they start to shrink, and as they start to shrink the trephine in the centre gets bigger. So eventually that parastomal hernia may come, but that's what we don't know yet."* [HCP: BRI0023, Lower GI, RDE]

"I have to say that I believe strongly that if you follow a patient up for long enough you will ultimately detect a parastomal hernia in them. I think that mesh prophylaxis in the short term will reduce the incidence of parastomal hernia formation, but if you follow that out long term, meshes shrink, and I still think that you will get parastomal herniation, but essentially what you're doing is merely delaying the inevitable…In terms of their ability to prevent parastomal herniation I can't tell you any good evidence… In terms of time periods it would be a matter of months, I would think, and they do shrink more than we think, at least by 50% or something a year. Sometimes the biologics can disappear altogether, and I've seen that.. I think the overall size of the mesh gets smaller, and that gets wider, so it shrinks that way, and that way, so that defect is…But I think, if you're putting a keyhole into any mesh, in mesh prophylaxis, or even as a repair, it's just going to shrink away, that circle is just going to get larger." [HCP: BRI0004, Lower GI, UHB]

Composition of mesh used

The interviews indicated that there were two main categories of mesh that participants used in stoma formation: synthetic and biologic. Synthetic is a man-made material (e.g. Polypropylene) and biologic is derived from biological matter such as porcine skin (e.g. Permacol) (114). The non-participant observations indicated that both synthetic and biologic mesh are used in clinical practice:

"The corners are trimmed off the mesh, making an oval shape. It looks like it's made of polypropylene." [Observation NB: BRI0021, End Colostomy, Laparoscopic, RDE]

"Biologic permacol mesh soaking in water is handed to the consultant. SpR retracts using two large langenbecks in the retrorectus space, having been positioned by the consultant." [Observation CM: BRI0030, End Colostomy, Open, UHB]

The choice of mesh composite was reported to sometimes be dependent on what was available, and/or surgeon preference:

"I use polypropylene mesh unless we've used biologic mesh somewhere else and we've got some off cuts, in which case I use a piece of biologic mesh but it goes retrorectus." [HCP: BRI0015, Lower GI, RDE]

Most surgeons had a rationale for favouring one type of mesh over another. Some believed that biologic mesh may resist infection better (participants felt that wound infections led to a greater risk of PSH); others believed synthetic was preferable because it formed rapid scar tissue (thus strengthen the abdominal wall). These ideas appeared to be based on surgical anecdote, and two surgeons commented that the evidence for superiority was inconclusive:

Respondent:" I think anytime you've entered the bowel, albeit it's small bowel, I'd be always wary about using mesh rather than sort of biomesh. I tend to use Permacol if we reinforce the stoma. Or indeed if I do a parastomal hernia repair unless it's a laparoscopic repair, in which case obviously you're not exposing the lumen of the bowel."

Interviewer: "Why do you think Permacol's beneficial"

Respondent: "Compared to mesh? Just because it resists infection better." [HCP: BRI0032, Lower GI, UHB]

"I think we have such limited evidence about use of synthetic mesh, even though people in the literature have suggested that synthetic mesh doesn't erode through the bowel, but I've seen meshes eroding through the bowel, so I'm reluctant to use it. From my anecdote, I think put biological meshes in all these patients and only one of them had a large enough hernia afterwards and I feel that the mesh probably slipped and that's the reason he got the hernia." [HCP: BRI0010, Surgeon, Lower GI, UHB]

"I would use in most patients a piece of polypropylene mesh in the retrorectus position…With the synthetic meshes the rate of tissue ingrowth is so rapid, and scar tissue formation is so quick, that you will find that you will have a fairly solid ring of tissue within four to six weeks, so that you get the protective effect relatively quickly. It's why most of the RCTs would demonstrate nowadays a protective effect with prophylactic mesh." [HCP: BRI0023, Lower GI, RDE]

Mesh size and shape

The optimal size and shape of the mesh inserted appeared to vary according to the surgeon. In the interviews, one surgeon suggested that the choice of mesh size should be equal to the space created for the stoma trephine in the abdominal wall. Another gave a precise size, while most other surgeons did not specify:

> *"Well on the basis that the mesh sits in a space that's longer than it is wide if you put your mesh in that space to fit in that shape then the pressure on the inside is pushing the peritoneum against the muscle contracting on the outside the mesh can't move anywhere."* [HCP: BRI0015, Lower GI, RDE]

> *"If we do that it involves developing a plane between the muscle layer and the posterior sheath and placing a very small piece of mesh 4cm by 4cm with polypropylene which you pull the stoma through."* [HCP: BRI0022, Lower GI, RDE]

There were observed differences in how surgeons deduced the size of mesh required. In the observation BRI0030, a measuring tape was used to size the retorectus space (space in between the rectus muscle and the posterior sheath), and then cut out a piece of mesh that was equal to that size. In another operation (BRI0021), a less precise estimate of the size of this space was gauged by eye and through palpating the defect:

> *"The consultant measures (using a ruler) the width and length of the retrorectus space and draws a rectangle in permanent marker of the edge of the mesh. The SpR holds the mesh while the consultant cuts using scissors."* [Observation CM: BRI0030, End Colostomy, Open, UHB]

"The corners are trimmed off the mesh, making an oval shape. It looks like it's made of polypropylene…The surgeon folds the mesh into quarters, then cuts off the corner, which makes a circular shaped hole in the centre. [Observation NB: BRI0021, End Colostomy, Laparoscopic, RDE]

The choice of shape also seemed to vary, with some surgeons using oval and others using rectangles. Another surgeon suggested that the mesh ought to be longer than it is wide (as seen in the above quotation from BRI0015). Most surgeons did not specify a particular preference for size or shape and referred to the mesh as a 'piece':

"I would use in most patients a piece of polypropylene mesh" [HCP: BRI0023, Lower GI, RDE]

Location of mesh and mechanism of creating space

There are four anatomical locations where mesh can be placed. The terminology used to describe these four locations varied between the participants. 'Inlay' is used to describe mesh placement within the rectus muscle defect. 'Onlay' describes mesh placement above the muscle. 'Sublay' or 'retrorectus' is used to describe mesh placement under and over the posterior sheath. 'Underlay', 'intraperitoneal' and 'IPOM' are all used to describe mesh placement under the fascia within the intra-abdominal cavity (56) (see Figure 12 for a pictorial description of mesh location obtained from (115)).

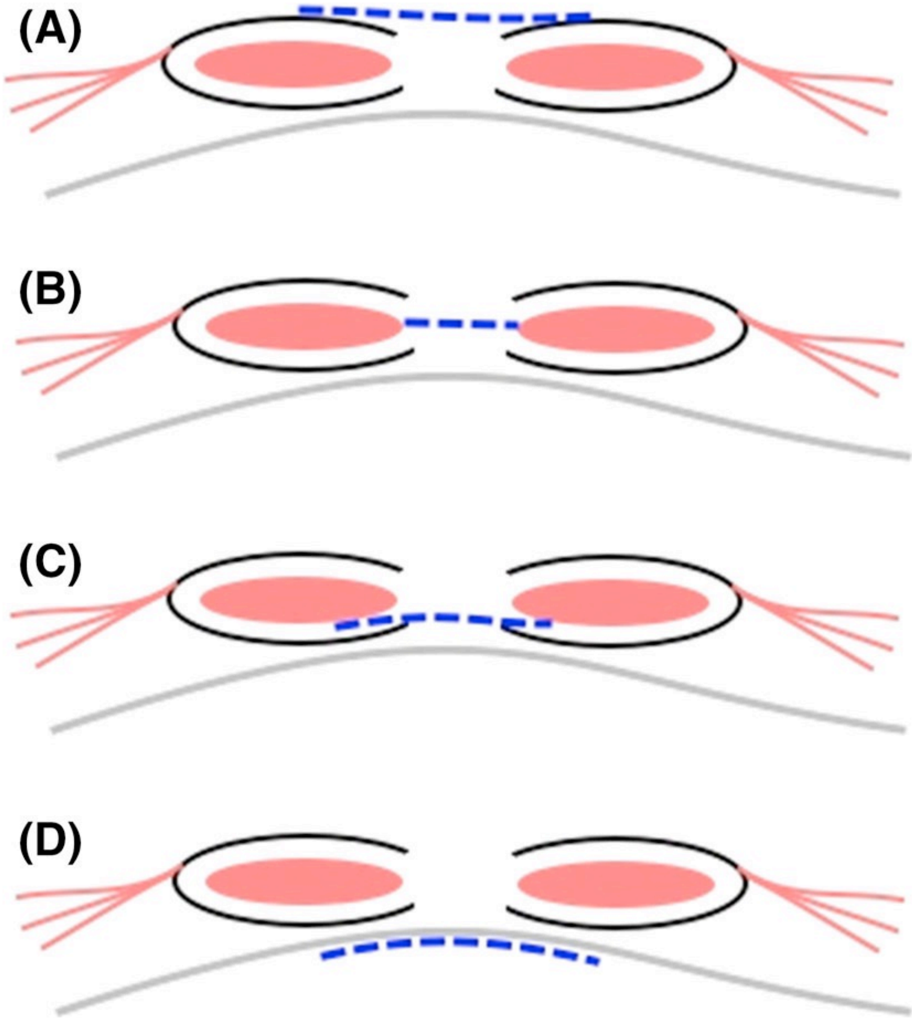

Figure 12: (A) Onlay (B) Inlay (C) Sublay/Retrorectus (D) Underlay/Intraperitoneal/IPOM. Reproduced with permission from Holihan et al, 2015 (115).

For both of the non-participant observations that used mesh (BRI0030 and BRI0021), the mesh was inserted into the sublay (retrorectus) position:

"The consultant then places the mesh with the retrorectus space." [Observation CM: BRI0030, End Colostomy, Open, UHB]

"Heiss used to insert mesh into retro-rectus space, manoeuvred with consultant's index finger." [Observation CM: BRI0021, End Colostomy, Laparoscopic, RDE]

Some surgeons theorised that the location of mesh insertion had potential implications for PSH prevention. Most seemed to favour the sublay (retrorectus) positioning, although the choice of location was also reported to be dependent on the surgical approach to the stoma formation (e.g. open or laparoscopic surgery). Some surgeons felt that they did not know enough about the literature to comment and others felt that there was not enough evidence to make a definitive decision about where best to place the mesh:

Interviewer: "Do you think either of those will make a difference with parastomal hernia rates?"

Respondent: "Depends where you put the mesh. We know if that if you put the mesh on the outside it makes no difference because we published that in 2009 and 2014 with our follow up. Whether putting it in the rectrorectus plane depends upon how the material behaves allowing the size of the hole." [HCP: BRI0015, Lower GI, RDE]

"Yes, and what technique you use to do that, so whether that is done intra-peritoneal, whether that's done in a retroperitoneal space, or in an onlay space… So, what I'm saying to you is there's about ten different ways of

> *doing something, which to anyone says that none of them are perfect, and that's never really been subjected to a trial of sufficient power, strength for us to know what the most effective technique is."* [HCP: BRI0004, Lower GI, UHB]

> *Interviewer: "Do you think location of the mesh makes a difference?"*
>
> *Respondent: "I don't have enough experience or know the literature to really tell you."* [HCP: BRI0018, Hepatobiliary, UHB]

> *"I think the evidence when they did all those prophylactic meshes, whether you put it intraperitoneal, retromuscular or anterior into the muscles, it didn't show any difference in the outcomes. I think it's just strengthening the muscle layer, but probably a large trial will tell us whether there's any difference. In an ideal world, I think you should probably put it either intraperitoneal or retromuscular. I think putting it anterior to the rectus sheath is probably pointless, you might as well not put it, I don't think it adds anything to it because the hernias start from the inside…Yes, it will just lift the mesh; it's not going to make any difference. It either has to be between the rectus and the posterior sheath or intraperitoneal where it might have a use."* [HCP: BRI0010, Lower GI, UHB]

Surgeons differed in their opinions about which mesh placement was preferred when adopting a laparoscopic approach:

> *"I would place prophylactic mesh laparoscopically through the trephine into the retrorectus space…For those patients who have had complex open surgery, where you're going to form an end stoma, you can approach the retrorectus space from the midline incision to place the prophylactic mesh,*

but realistically there is no difference between open and laparoscopic formation." [HCP: BRI0023, Lower GI, RDE]

"When I'm doing laparoscopic I use intraperitoneal mesh" [HCP: BRI0010, Lower GI, UHB]

There also appeared to be disagreement regarding intraperitoneal (ipon, underlay) placement of the mesh, with some favouring this, and others considering it a safety risk.

"When I'm doing laparoscopic I use intraperitoneal mesh and it gives you that extra security because that mesh is where the muscle loses strength, so even though the muscle may become lax around the bowel, that mesh is going to stay the same around the bowel. There is less chance of the bowels slipping down." [HCP: BRI0010, Lower GI, UHB]

Respondent: "What then becomes important would be safety considerations and longer-term consequences of having mesh in the intraperitoneal position in contact with bowel."

Interviewer: "So you get erosions?"

Respondent: "Erosion, fistulation, etc., and how you've attached that mesh, particularly if you do intraperitoneal placement, either as a keyhole or as a Sugarbaker type procedure, the fixation that you use comes with its own consequences." [HCP: BRI0023, Lower GI, RDE]

How the space is created and route used to position mesh

The non-participant observations showed that if the surgeon was not placing the mesh into the intraperitoneal position, different techniques could be used to create the space between the abdominal wall layers where the mesh was being placed. The observations showed examples of surgeons creating the space by hand, through blunt finger dissection, or through surgical dissection using diathermy.

> *"Single- index finger feels and sweeps around breath of trephine to create a space in the retrorectus space."* [Observation CM: BRI0021, End Colostomy, Laparoscopic, RDE]

> *"The surgeon uses their finger to create a space, and further fibres of muscles/fascial tissue is cut with diathermy…The surgeon uses a clip to guide the mesh into the pocket that they have created for it. They use their fingers to smooth the mesh out and get it into position."* [Observation NB: BRI0021, End Colostomy, Laparoscopic, RDE]

> *"It looks as though a 'pocket' has been created in the layers of the anterior abdominal wall (through the midline incision). The Littlewoods seems to be attached to the posterior sheath, and the Langenbecks lifting up the anterior sheath. The surgeon places a ruler over the 'posterior sheath' layer."* [Observation NB: BRI0030, End Colostomy, Open, UHB]

It was observed that the mesh could also be placed into the space created using different methods. During an observation of an open procedure, the mesh was placed through the midline incision. For an observation of a laparoscopic procedure, the mesh was placed through the trephine. This difference in technique was also alluded to during an interview with BRI0023:

"I would place prophylactic mesh laparoscopically through the trephine into the retrorectus space…For those patients who have had complex open surgery, where you're going to form an end stoma, you can approach the retrorectus space from the midline incision to place the prophylactic mesh, but realistically there is no difference between open and laparoscopic formation." [HCP: BRI0023, Lower GI, RDE]

"I would tend to put it either from above, either under the fascia or just on top of the fascia from above rather than from inside." [HCP: BRI0036, Lower GI, UHB]

"Ideally in a… underneath the fascia if it didn't involve opening it up anymore but um for a simple re-enforcement I would… an onlay maybe sufficient if… what you don't wanna do is do more dissections to try and get this mesh in that then gives you a bigger hole so that's what I'd be… it depends on how easy it was to do that. I would be happy with an onlay in that circumstance I wouldn't with a parastomal hernia repair." [HCP: BRI0036, Lower GI, UHB]

Mesh trephine

This work identified two different approaches for passing the bowel through the mesh. One method, observed in both observations where mesh was used and reported during the interviews, was to create a 'keyhole' in the centre of the mesh. During the interviews, some surgeons advocated the modified Sugarbaker technique. This involves an intraperitoneal placement of the mesh and not creating a keyhole in the mesh. Instead the mesh is secured as an intact piece over the bowel (Figure 13). The modified Sugarbaker is a variation on the Sugarbaker technique that was originally used for PSH repair. The Sugarbaker technique was modified around the trephine opening to guarantee an adequate overlap between the mesh and the fascia (116). However, a surgeon (BRI004) reported that this was not a technique in use.

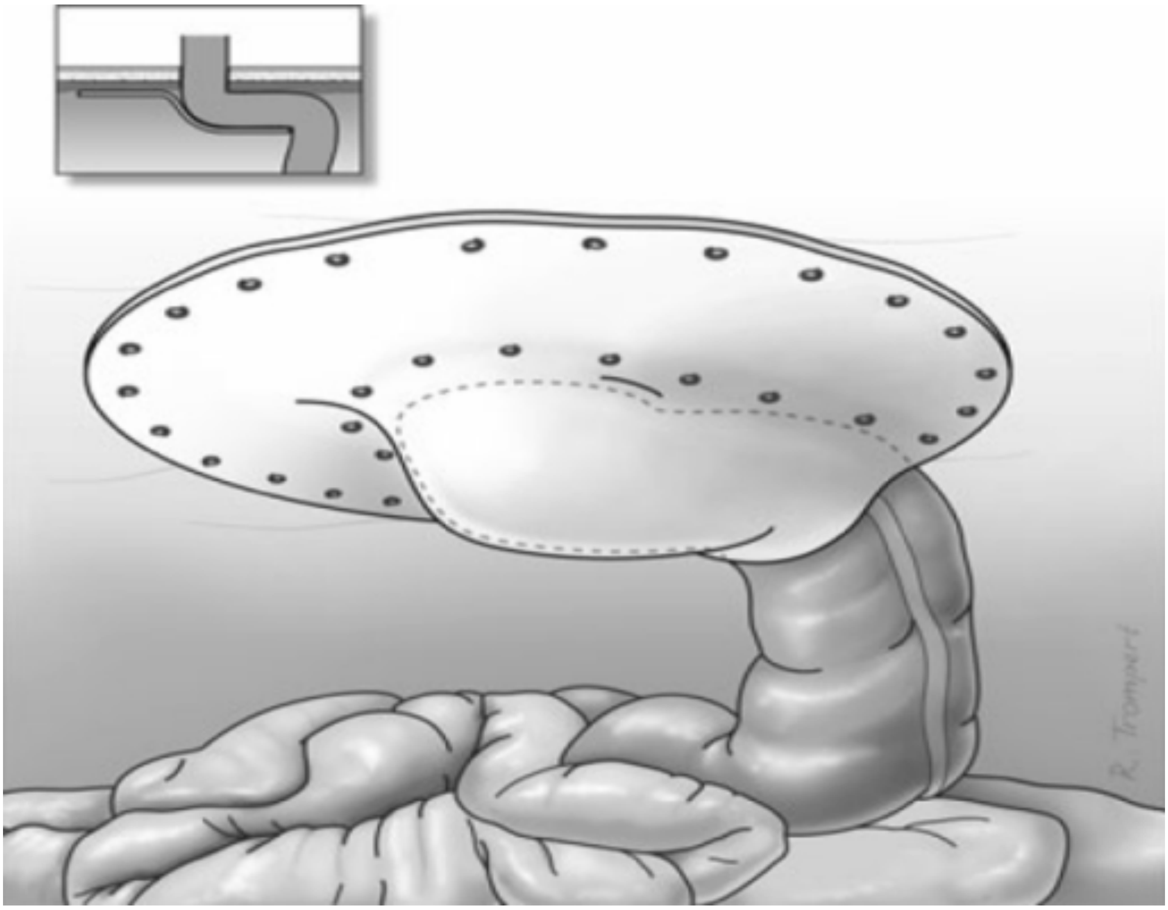

Figure 13: Laparoscopic modified Sugarbaker technique. Reproduced with permission from Hansson et al, 2013 (80)

"Fold mesh over into quarters and cuts the corner that is at a right angle off to create circular key hole." [Observation CM: BRI0021, End Colostomy, Laparoscopic, RDE]

"Yes, and what technique you use to do that, so whether that is done intra-peritoneal...with the keyhole defect, whether you do a Sugarbaker technique. So, what I'm saying to you is there's about ten different ways of doing something, which to anyone says that none of them are perfect, and that's never really been subjected to a trial of sufficient power, strength for us to know what the most effective technique is". [HCP: BRI004, Lower GI, UHB]

Interviewer: "I was just wondering if you knew anyone who performed the initial Sugarbaker one described in the literature, rather than modified?"

Respondent: "When they just tack onto the fascia ledges? … No, I don't, I would just cover the whole defect. Again, this is the same thing, people's definitions of what the original techniques are vary." [HCP: BRI004, Lower GI, UHB]

Respondent: "But I think, if you're putting a keyhole into any mesh, in mesh prophylaxis, or even as a repair, it's just going to shrink away, that circle is just going to get larger…No, the trephine gets larger, what I think, [I know you can get this] for the purpose of your interview, but if let's see you were using a trephine technique as [the] mesh, as a preventative feature, and you do that, this is what I think happens, in terms of the shrinkage. I think the overall size of the mesh gets smaller, and that gets wider, so it shrinks that way, and that way, so that defect is…

Interviewer: "So it contracts… Do you think that's a reason why the Sugarbaker technique would be superior to-"

Respondent: "Yes, so that's what I think, why Sugarbaker would be superior. That said, I don't think it's 100% effective. That's what I would use as a method of mesh prophylaxis and permanent stoma." [HCP: BRI004, Lower GI, UHB]

Surgeons theorised there to be some risks associated with the modified Sugarbaker technique. These risks included difficulty with follow up colonoscopy and obstruction:

"Whether I, Sugarbaker I know has exponents for it, but it makes me very nervous in terms of causing obstruction later on" [HCP: BRI0032, Lower GI, RDE]

Respondent: "My only reservation about that technique is if I'm doing it on a patient that, say, had an AP resection for cancer. If you are lateralising the bowel a bit, you also have to survey the patient's colons after the cancer surgery, to look for polyps or further cancers, I think actually makes colonoscoping the patient more difficult ___ I'm not sure. So I think that might be an issue with endoscopic surveillance if you do the Sugarbaker technique. I can't tell you whether that's true or not, it's very early days.

Interviewer: And do you perform modified Sugarbaker?

Respondent: Yes." [HCP: BRI004, Lower GI, UHB]

Variations in the shape of the keyhole used were also reported and observed. The two options identified during data collection were cruciate and circular/oval shapes. While the shape of the mesh key-hole was not discussed specifically, some surgeons felt strongly that circular incisions generally were superior due to the tangential forces applied being more evenly distributed, which in turn meant the incision was less likely to tear/widen overtime.

> *"If you've got a circular incision maybe you've got a bit more strength around the radius of it, rather than splitting it."* [HCP: BRI0032, Surgeon Lower GI, RDE]

Securing the mesh

The interviews and observations identified multiple variations in how mesh may be secured to the abdominal wall. The most prominent categories reported during the interviews included tacking, suturing and not securing the mesh. During the observations, only suturing (Observation BRI0030) and not securing the mesh (Observation BRI0021) were observed. The context of the stoma formation appeared to influence which of these options was selected, as demonstrated by the quotation below from BRI0022.

> *'When I do it laparoscopically I just use the tacks. If I'm doing open surgery I use stitches."* [HCP: BRI0022, Lower GI, RDE]

Some surgeons reported choosing not to secure the mesh when using a retrorectus position for the mesh, but rely on the forces acting on the abdominal wall as well as the stoma through the keyhole of the mesh to stabilise the its position.

> *"If I put it in the retrorectus space it can't go anywhere because you've made a hole in the middle of the mesh. You've bought the bowel through the hole…Well on the basis that the mesh sits in a space that's longer than it is wide if you put your mesh in that space to fit in that shape then the pressure on the inside is pushing the peritoneum against the muscle contracting on the outside the mesh can't move anywhere".* [HCP: BRI0015, Lower GI, RDE]

The participants reported possible variations in the type of tack or suture (absorbable and non-absorbable) used, as well as variations in the density of the tacks or sutures (single or double crown). One surgeon (BRI0023) theorised that there may be a difference between absorbable and non-absorbable tacks because of the way the tacks adhere to the bowel, however the surgeon did not think that the method of securing the mesh would alter mesh shrinkage. The same surgeon also theorised that transfascial suturing is likely to be the least effective method, based on their knowledge of the behaviour of sutured mesh in other scenarios.

> *"I just use one circle (of tacks)."* [HCP: BRI010, Lower GI, UHB]

> *Interviewer: "Do you think if you were to do it in an intraperitoneal position, with tacking, would that affect the shrinkage or the changing the shape of the mesh?"*
>
> *Respondent: "No, because the changing the shape of the mesh is governed by fibroblast ingrowth, as the fibroblast deposit their extracellular matrix around, and contraction then occurs. How you staple the mesh ___ does not affect whether or not it then forms its shrinkage. That will always happen…Anyone who has done any sort of surgery on patients who have had previous laparoscopic incisional hernia repairs, intraperitoneal placement, will tell you that even though those patients have had surgery where they have double-crown stapling techniques, those meshes can still scrunch up into a tiny little ball, because that's the way your body treats them."*
>
> *Interviewer: "Do you think the method of tacking or suturing makes a difference, or the material used makes a difference, to parastomal hernia rates?"*

Respondent: "Quite possibly. If you just do transfascials it's probably not as good. If you use permanent stapling, or spiral tackers, they are probably the best option. The absorbable ones I think you're likely to get a degree of detachment. We know from the Danish hernia registry, for incisional hernia repair recurrence rates and re-operation rates are higher with transfascial suturing and for absorbable tackers, unabsorbale tackers. That's fairly well-established by national registry data." [HCP: BRI0023, Lower GI, RDE]

"They're the tackers. They're the spiral tackers. Or variants on a theme, whether they're absorbable tackers, stapling devices, which can be absorbable. All of the major device manufacturing companies will have something. Whichever one you use bowel can adhere to it, and it can adhere to the mesh. So they all come with their own risks." [HCP: BRI023, Lower GI, RDE]

Interviewer: "One thing I have written is the different ways to tack to mesh. I've used single-crown and double-crown. Are there any other variations?"

Respondent: "Yes, transfascial suturing…For when I do parastomal hernia repair, and I do a Sugarbaker technique, I will use transfascial sutures to place the mesh as well, and that acts partially as a fixation. I will do that and some stapling device as well, and the Sugarbaker is associated with its own unique stapling pattern, because of the way in which it overlies the bowel." [HCP: BRI023, Lower GI, RDE]

3.2.6 Non-technical factors

'Non-technical factors' was an umbrella term, used in this study to refer to the associated concomitant interventions such as: pre-, peri- and post-operative care; the context in which a surgical intervention is delivered; and the expertise with which it is delivered by the surgeon(s) and their team. Six main categories of non-technical factors were identified as being potentially important in PSH development based on the interviews and observations. One overarching category, patient factors, will be discussed below.

3.2.6.1 Patient factors

'Patient factors' refers to patient characteristics that may act as risk factors or may be protective for PSH development. Patient factors were felt to be important by both surgeons and the stoma nurses alike. The identified patient factors are discussed below.

Diseases of the connective tissue

Conditions such as abdominal aortic aneurysm, previous hernias, and diverticular disease were suspected by the surgeons and stoma nurses interviewed to impact of PSH rates:

> *"Yes definitely, absolutely um the more surgery they have the more at risk they are of a hernia and generally speaking a patient whose had a hernia I tend to find the serial offenders of then getting hernias."* [HCP: BRI0035, Stoma Nurse, RDE]

> *"Patients with diverticular disease, a connective tissue disorder, for those patients incisional hernia rates seem to be higher, and I'm fairly certain parastomal hernia rates would be higher. The whole concept of herniosis, this non-specific connective tissue disorder, is I think relatively well-established. I think they're probably at greatest risk."* [HCP: BRI0023, Lower GI, RDE]

> *"If you've had an aneurysm repair and you've got perforated diverticular disease your risks of incisional hernia are sky high and your risks of parastomal hernia are sky high."* [HCP: BRI0015, Surgeon, Lower GI, RDE]

> *"Collagen defects. They're not the classical collagen defects that you know that define Marfan's, that sort of thing, but they're more subtle than that, I think."* [HCP: BRI0018, Surgeon, Hepatobiliary, RDE]

Patient age

Both surgeons and stoma nurses felt that increasing age was a risk factor for developing a PSH. One of the stoma nurses, BRI0003, felt that this was due to the general "looser" quality of the tissue in an older person:

> *"I think patients who are old tend to get parastomal hernias, whatever you do."* [HCP: BRI0010, Surgeon, Lower GI, UHB]

> *"I think to me that's it. I think, actually, age probably is quite a huge contributing factor because, obviously, as we get older, everything sort of*

loosens and slackens a bit. I definitely think weight is probably quite a big factor." [HCP: BRI0003, Stoma Nurse, UHB]

Diseases and risk factors that may affect tissue healing

Diseases such as diabetes, cardiovascular disease and other risk factors such as use of steroids, chemotherapy, abdominal wall radiotherapy as well as smokers were suspected to increase the risk of PSH due to their impact on wound healing. These have been summarised in Table 11: Diseases and risk factors for poor tissue healing.

Table 11: Diseases and risk factors for poor tissue healing

Diseases and risk factors that may affect tissue healing	
Cardiovascular complications	*"Cardiovascular complications might impair your perfusion of the tissues in that area, might make a stoma rate increase. [Respiratory ones 0:39:14] might mean that if [you're less likely to get those you might have] less systemic sepsis, so on and so forth. Therefore, I can imagine sepsis, either locally or systemically, might impact on tissues with oedema and so on… I suspect obesity, diabetes. I'm less clear on age. I think more actually physiological age rather than chronological age has more import. Significant comorbidities. Cardiovascular, respiratory, and diabetes I think are the main things."* [HCP: BRI0018, Surgeon, Hepatobillary, RDE]
Obesity	*"Obesity, any other factors that affect healing generally, so comorbidity, renal failure in particular."* [HCP: BRI0032, Surgeon Lower GI, RDE]
Renal failure	*"Obesity, any other factors that affect healing generally, so comorbidity, renal failure in particular."* [HCP: BRI0032, Surgeon Lower GI, RDE]
Poor nutrition	*"And then in terms of patients, those who have got any factors that will cause poor wound healing, so like, poor nutrition, smokers, lung disease, heart disease, diabetes, people who are on steroids. Those are all things that are associated with higher risk of parastomal hernia as well."* [HCP: BRI0009, Surgeon, Upper GI, UHB]

Diseases and risk factors that may affect tissue healing	
Smoking	*"And then in terms of patients, those who have got any factors that will cause poor wound healing, so like, poor nutrition, smokers, lung disease, heart disease, diabetes, people who are on steroids. Those are all things that are associated with higher risk of parastomal hernia as well."* [HCP: BRI0009, Surgeon, Upper GI, UHB]
Lung disease	*"And then in terms of patients, those who have got any factors that will cause poor wound healing, so like, poor nutrition, smokers, lung disease, heart disease, diabetes, people who are on steroids. Those are all things that are associated with higher risk of parastomal hernia as well."* [HCP: BRI0009, Surgeon, Upper GI, UHB]
Use of steroids	*"Patients who have IBD, particularly if they've had long courses of steroids before they get the stomas, yes, I think they're likely to be higher... The downside is that most of the patients who get cancer of the type that needs this type of situation, where they need a stoma frequently, they're elderly, so they don't have as good quality tissue, so a higher risk of parastomal hernia. They also have a lot of comorbidity."* [HCP: BRI0023, Lower GI, RDE]
Radiotherapy	*"You will be looking at patients who have had much more of their abdominal wall irradiated. If they then have to have stomas formed, because they get the consequences of their radiotherapy, things like rectal/vaginal fistulas are quite common. So you advise them to have a stoma formed upstream. Those patients, yes, quite possibly a greater risk of parastomal hernias, I would have thought."* [HCP: BRI0023, Lower GI, RDE]

Diseases and risk factors that may affect tissue healing	
Chemotherapy	*"If a patient then goes onto have chemotherapy that can also cause other issues, you know it makes the bowel more friable and I just think it makes everything very delicate and thus hernia can protrude really quickly."* [HCP: BRI0035, Stoma Nurse, RDE]
Diabetes	*"Yea all the wounds healing ones so you know diabetic, immunio-compromised, steroids, uh smoking."* [HCP: BRI0036, Surgeon, Lower GI, UHB]
Inflammatory bowel disease	*"Patients who have IBD, particularly if they've had long courses of steroids before they get the stomas, yes, I think they're likely to be higher... The downside is that most of the patients who get cancer of the type that needs this type of situation, where they need a stoma frequently, they're elderly, so they don't have as good quality tissue, so a higher risk of parastomal hernia. They also have a lot of comorbidity."* [HCP: BRI0023, Lower GI, RDE]
Immunocompromised	*"Yea all the wounds healing ones so you know diabetic, immunio-compromised, steroids, uh smoking."* [HCP: BRI0036, Surgeon, Lower GI, UHB]

Patient factors relating to the indication of surgery

Conditions relating to the surgery itself were also thought to be potentially important for PSH prevention. One surgeon theorised that if you were creating the stoma for intra-abdominal infection then the patient may be more likely to develop a wound infection which would have a negative impact on wound healing, which in turn could increase the risk of PSH. Others discussed how an obstructed oedematous bowel may also increase the risk of PSH development as this would require the surgeon to widen the stoma trephine to accommodate the swollen bowel:

> *"If you're operating on somebody with faecal peritonitis and they get wound infections, they might be more likely. So emergency surgery, I think obstruction probably and peritonitis are probably the two factors that result in parastomal hernia."* [HCP: BRI0010, Surgeon, Lower GI, UHB]

> *"I tell you what would make think that they were going to have a parastomal hernia, is if the stoma was formed in an emergency setting, and the patient, I knew, had had obstructive symptoms."* [HCP: BRI0004, Surgeon Lower GI, UHB]

> *"So, if you're doing this as an emergency where there is dialation about, for whatever reason, whether there's been obstruction. The bowel is very oedematous and I know for a fact that I certainly make larger incisions, larger cruciates in that case, because what I don't want is the patient to have ischemia because of constriction at the fascia. I know for a fact that I do that because I don't want to take them back to theatre to revise the stoma firstly, but I know that doing that will increase their risk once the*

oedema settled down again of parastomal hernia." [HCP: BRI0004, Surgeon Lower GI, UHB]

Conditions that raise intra-abdominal pressure

Conditions that raised intra-abdominal pressure, or cause the patient to have a weaker abdominal wall that is unable to resist raised intra-abdominal pressure were also thought to increase the risk of PSH development by both surgeons and stoma nurses.

> *"I think obese patients or patients with chronic coughs which is going to your internal abdominal pressure. I think like any of these hernia things it is multi-factorial based on your genetics, the surgeon factors and the post-operative infections, cough and anything else that will increase internal abdominal pressure."* [HCP: BRI0022, Surgeon, Lower GI, RDE]

> *"I think abdominal distention definitely can contribute to hernia and I think because it stretches the muscle wall I think it allows hernias to be… pop through easier."* [HCP: BRI0035, Stoma Nurse, RDE]

> *"We talk about, you know, because this time of year it's the gardening and all that (Laughter), but we do, if we know that they've got a job that may involve a bit of lifting, then we would make sure that they get fitted with a support garment, but you cannot guarantee that that is actually going to stop it, either."* [HCP: BRI0003, Stoma Nurse, UHB]

Conditions that reduce the tone or integrity of the abdominal wall

Most of the surgeons and all stoma nurses felt that obesity was a risk factor for PSH development. This was reported to be through various mechanisms such as the impact on the 'tone' of the abdominal wall, an increased risk of wound complications, increased challenge in creating the stoma, and larger patients requiring larger stoma trephines.

> *"So patients that have poor diet and smoke and things like that and they're a bit more overweight I reckon personally are more predisposed to getting hernias just because there's no tone there and you know body habitus so yea definitely there are lifestyle things that can affect hernia, absolutely um…"* [HCP: BRI0035, Stoma Nurse, RDE]

> *"The fatness of the patients…well, anything that would give you a weak anterior abdominal wall."* [HCP: BRI0001, Surgeon, Upper GI, UHB]

> *"Yes, I try very hard not to make stomas in morbidly obese patients. But you don't always have a choice. Because I think they are a group that are always going to have wound problems. That's a situation where I do almost think it's inevitable, in emergency surgery in morbidly obese patients or major surgery in morbidly obese patients. There always seems to be some sort of wound complication."* [HCP: BRI0009, Surgeon, Upper GI, UHB]

> *"I think in view of the factors we discussed particularly patient factors and especially obesity are probably more relevant. Whether it's the obesity itself that causes it or whether it's just that big people, it's awkward to get the*

bowel through the abdominal wall so you make a bigger hole, so I'm not sure if it's direct or indirect. Probably a bit of both."[HCP: BRI0032, Surgeon Lower GI, RDE]

"The patient's body habitus is crucial and so the big patients we're doing it on they do get parastomal hernias, a big, larger abdominal wall you have to make a reasonable size cut so you don't just strip all the mesentery off as you draw it through. Um and they have a very high tendency to parastomal hernias." [HCP: BRI0036, Surgeon, Lower GI, UHB]

Being a post-partum female was also considered a risk for PSH due a subsequently weakened abdominal wall:

"Postpartum females are more at risk if having a change in the abdominal wall physiology." [HCP: BRI0004, Surgeon Lower GI, UHB]

"Ladies who have had babies I have noticed tend to get hernias and I think that it kind of goes with the patients that have had abdominal distention, you know they get a bit sort of pulled about a bit and things aren't quite as tight as they usually are on the abdominal so then a hernia is really quite likely to, to…" [HCP: BRI0035, Stoma Nurse, RDE]

Other factors that the participants felt may impact on the integrity of the abdominal wall included previous operations:

"Other things that also I definitely feel contribute to hernia is the amount of times they've had surgery as well, the amount of times that the abdominal wall has been sort of punctured if you like um the healing is sort of um uh it never heals as well as a sort of untouched abdomen if you know what I mean." [HCP: BRI0035, Stoma Nurse, RDE]

Having good muscle tone as a preventative factor

Some of the stoma nurses felt strongly that having a good level of pre-operative muscle tone was an important preventative factor for PSH development:

> *"Pre operatively if the patient is generally quite a fit active person and they've got sort of a good muscle tone and things like that they, you know they look after themselves um which generally falls in the younger category patients then they, my experience is but I haven't seen many younger patients with hernias but for sure the fitter the patient is the less likely they get a hernia…hand in hand with you know they're just more fitter and their abdominal muscles are more stable and you know they're more robust and I suppose the more they're used the more tighter the muscles get and then less likely to get an hernia."* [HCP: BRI0035, Stoma Nurse, RDE]

3.3 The long-list

Many themes were identified through the process of coding both the literature review and the mixed qualitative methods work. The long-list of factors that may be relevant to the CIPHER study was developed by combining the themes identified through both phases of data collection. NB and CM reviewed each theme and compared the findings of the two data collection phases. They iteratively refined the wording of the themes and organised the themes into categories, excluding overlaps, and combining themes where possible. This was a long and iterative process as the coding framework from both phases interacted and created more complexity within the framework of overarching themes, category themes, and themes. Themes also did not always use the same language and were difficult to untangle for the more complex concepts. For example, many surgeons referred to the modified Sugarbaker technique as 'Sugarbaker' whereas in the literature the two were distinct with different meanings.

Overall, 265 unique factors (180=technical, 85=non-technical) were identified. This long-list of individual data items were arranged into tables by NB and CM to present the data in a format that was easy to manage for the consensus meeting. Using NB's surgical expertise, the formatting of the long-list into tables resulted in the splitting and condensing of certain data items. CM and NB also supplemented the long-list with the addition of 'other' as a possible response category where appropriate. The long-list was reviewed by two senior colorectal surgeons from different centres across the UK who were not attending the consensus meeting. This was to check for CM and NB's understanding of terminology and also to ensure that all factors had adequately been identified during this research. Additional data items suggested by the two surgeons are listed below in Table 12.

Table 12: List of additional items

1	Stoma formed in isolation or part of another procedure
2	Intraoperative epigastric vessel damage
3	Intraoperative 'other' vessel damage
4	Abdomen re-inflated following trephine formation
5	10mm port sutured closed using small bite closure
6	10mm port sutured closed using large bite closure
7	10mm port not sutured closed
8	5mm port sutured closed using small bite closure
9	5mm port sutured closed using large bite closure
10	5mm port not sutured closed
11	Type of stoma formed: Loop stoma +/- Rod
12	Type of stoma formed: Loop end (Abcarian)
13	Section of bowel used to form the stoma: Descending colon
14	Waist circumference (documented via CT scan as an alternative measure of obesity)

The final long-list contained 298 data items formatted so that the themes were ready to be transposed into the CRFs. These were subsequently presented to the consensus meeting participants and can be reviewed in Appendix 7.

3.4 Development of the short-list: gaining consensus

A consensus meeting of senior surgeons and a Professor of Health Services Research was performed on the 5th December 2016 with LR, NB and CM in attendance. The demographics for the consensus meeting are provided in Table 13.

Table 13: Demographics of consensus meeting attendees

Specialty	Trust	Grade
Lower Gastrointestinal	Royal Devon and Exeter	Consultant
Lower Gastrointestinal	Queen Elizabeth Hospital	Consultant
Lower Gastrointestinal	Bristol Royal Infirmary	Consultant
Lower Gastrointestinal	Royal Surrey County Hospital	Consultant
Lower Gastrointestinal	Southmead Hospital	Trainee
Professor of Surgery	Bristol Royal Infirmary	Consultant
Professor of Health Services Research	Bristol Royal Infirmary	Non-clinician

Consensus methods identified 97 essential items and 17 desirable items. Additional amendments to the list included wording changes, items being condensed into one and additional response categories to create exhaustive lists. Seven added data items suggested during the consensus meeting were also included. These additional items that were considered to be of importance to collect during the CIPHER study, but not identified during the phases of data collection, were as follows:

1) Name of the primary procedure
2) Indication for surgery
3) The specialty of the person marking the stoma site
4) Removal of anterior sheath during trephine formation
5) Removal of posterior sheath during trephine formation
6) Development of a post-operative haematoma
7) Development of post-operative mucocutaneous dehiscence

The consensus process also highlighted the importance of using multiple phases of data collection and the value of using insights from the qualitative interviews and literature work to explain the 'theories' around why certain factors might influence risk of PSH formation. For example, during the consensus meeting the surgeons considered the data item regarding pregnancy to be not required. CM then discussed the rationale behind this data item (based on interviews with the stoma nurses), which facilitated the decision to eventually include this item in the short-list. CM also used the direct observation data to challenge the surgeons' assumptions about current practice. For example, one surgeon reported that a data item was not required in the short-list because they felt that no one in clinical practice would perform that particular action. However, from the non-participant observations CM knew that this was in fact a variation that existed in real-life practice and was able to challenge the surgeon's views based on the findings from the qualitative analysis.

While consensus on the classification of most of the data items was easily found, there were items that were more problematic. For several of the items long deliberation was had, where the panel held conflicting views. An example of this are the data item on 'bowel mobilisation'. While the surgeons all agreed that adequate bowel mobilisation was important for stoma health, it was difficult to determine a method for which information could be collected on this item. Input from BR, the professor of health science research, confirmed that bowel mobility would be difficult to measure intraoperatively and data on this would likely be unreliable and not useful in the main analysis. Subsequently, this item became 'undesirable'. For some of the data items consensus was not clear, where this was the case NS asked for the panel to vote for either of the three classifications by raising their hand. While this method resolved some of the conflict, for a small proportion of the data items, disagreement was ongoing. Where this was the case, these data items would be classed as 'desirable' and re-discussed at the end of the meeting. For 17 data items, further discussion did not resolve the differing views and it was decided that these data items would remain desirable' and they would only be included in the short-list if at a further meeting between the CTEU and the CI (NS) it was deemed feasible to do so.

3.4.1 Iterations to the short-list

Constructing the CRFs from the short-list of data items involved two meetings with the study management group (CTEU), a team with extensive expertise in study design and management, and the CI of the CIPHER study (NS). The study management group provided valuable insights regarding what measurements would be achievable. Due to the number of items deemed 'essential' during the consensus meeting it was decided that the majority of 'desirable' items could not be included in the final CRFs. Each data item was considered individually, and only four of the fifteen desirable items were included in the final CRFs. The four desirable data items selected were included because they were simple and the team felt that collecting them would not add increased burden to the study participants. An example of a simple data item to collect, that was ultimately included in the CRF, was the data item on parity for women (number of pregnancies carried to a viable term). This decision was supported by the members of the consensus meeting, who were contacted latterly. Amendments were made to phrasing and formatting of the essential items but the content/meaning of the essential items remained unaltered. The short-list can be reviewed in Appendix 8.

3.5 Final case report forms

The CRFs are currently in their final stages of development. During a meeting between the study management group and CM it was decided that the format of the CRFs would be optimal as online electronic CRFs that could be completed in theatre. Being electronic has the advantage of filtering the questions so that the questions that are irrelevant are not presented to the data entry person. E.g. If a mesh is not used then the following question regarding the composite of the mesh will not be available. Since writing this thesis the electronic CRFs have been completed and the CIPHER study opened in 23 centres.

CHAPTER 4. DISCUSSION

This chapter is arranged into five sections. The first section discusses the context and relevance of this work. The second section summarises the research performed during this MSc and its key findings. The third section discusses the limitations of this study. Section four considers the impact of the research on this MSc. Finally, a fifth section performs a critical assessment of this MSc using a qualitative approach and suggests future work to improve this methodology

4.1 Context and relevance of this research

The complexity of surgical interventions is a challenge to study design. There are challenges with how an intervention is described in the protocol and challenges in how to monitor protocol adherence during a study. If not enough is known about how the intervention is delivered and in what context there will be implications for interpreting the results of a study which may be criticised. This is an important consideration for both RCTs and observational study design.

Feasibility work has been recommended by the MRC to resolve this issue, advocating the use of qualitative and quantitative methods within exploratory studies to achieve this aim. Further work from Blencowe et al described a typology to be used to deconstruct surgical intervention and establish how much standardisation is required for each component (44). However, it is not clear how to apply this recommendation to surgical study design CRFs and this had not been previously done. This MSc was performed within the feasibility phase of the CIPHER study. It extended Blencowe's methods to establish how to develop CRFs to capture the form and delivery of a surgical intervention within its natural setting. This will enable the CIPHER investigators to determine how the individual components of a complex intervention and other non-technical considerations affect outcomes when they are assessed in the CIPHER study. It also will establish a method that others can use in different studies.

Qualitative methods have been previously used to understand a complex surgical intervention at the design phase of an RCT (44). Blencowe et al (44) employed 'case study' methodology to identify the key components of a complex surgical intervention (gastric bypass surgery) and subsequently provide guidance on how to standardise and deliver the complex intervention within an RCT (the By-Band study). The term 'case' referred to the unit of analysis and comprised of non-participant observation in theatre, with video recording of the surgery followed by in-depth interviews with the operating surgeon. The case study methodology employed by Blencowe et al, had a low number of participants (n=8) raising concerns for the research team about the generalisability of findings. However, each case yielded very rich data that was studied intensively and the focus of the work was to provide an understanding of the surgical intervention within its natural setting, not to generalise the results which is often a focus of quantitative work as opposed to qualitative work.

This MSc modified the work by Blencowe et al, for a new application within a different context, a surgical cohort study. This work demonstrated how understanding the heterogeneity of a complex intervention is of benefit to cohort study design, where the aim of the study is to determine how individual components and contextual factors may act as risk factors for a complication of the complex intervention. Blencowe et al, used qualitative methodology to inform RCT design with the focus to describe how the intervention was to be delivered and monitored. Whereas the emphasis of this MSc was to design CRFs so that data collection can document natural practice and record all permutations of the surgery that may influence the selected outcome, to comprehensively identify key risk factors.

This MSc modified the approach used by Blencowe et al, to explore the phenomenon of stoma formation. It consisted of two key modifications to meet the research needs of the CIPHER study. Firstly, a literature review was performed in addition to the mixed qualitative methods. Performing a literature review prior to the exploratory work enabled the identification of the 'known' variations' in how stomas are surgically formed and in what context. For example, historical variations that were more prevalent during the evolution of the surgical procedure (e.g. closure of the lateral spaces using extraperitoneal tunnelling of the intestine). It also identified experimental variations that were being described and performed in other countries by specialist teams (e.g. mechanical trephine making device) that local teams (UK) may not have yet encountered. Performing the literature review as the first stage also helped to structure the data collection methods used in the latter stages, and enabled CM to develop an understanding of complex terminology (e.g. anatomical descriptions of the mesh placement) that is commonplace within surgery.

The second modification was the design of the qualitative data collection from case study methodology to mixed qualitative methods. This MSc used the same components of investigation (observation, video-recording and semi-structured interview) however the unit of 'case' was amended. In this MSc the unit of 'case' (paired observation and interview of the same surgeon) where necessary became two distinct units (unpaired observation and interview with multiple surgeons and stoma nurses). This represented a divergence from this MSc's original planned methodology as pairing observation with an interview was quickly recognised to be impractical. This was due to the challenges of scheduling interviews with surgeons following observations, and the unplanned nature of stoma formations performed by non-colorectal surgeons (i.e. emergency out of hours procedures).

This modification allowed a more flexible approach to be used for sampling as interviews could be performed with healthcare professionals with and without the need for a preceding observation. Without this modification, the sample size of this study would have been significantly reduced. Importantly the views of healthcare professionals outside the unit of 'case' (i.e. not present in the observed procedure) would not have been collected. This would have been detrimental to the richness of the data as it would have excluded stoma nurses as well as non-colorectal surgeons, who typically operate under emergency out of hours conditions and therefore did not have any procedures observed. A disadvantage to this modification was that it risked losing the insight of the observation that an immediate interview with the operating surgeon may have provided, potentially reducing the richness of the data. The research team recognised this issue and wherever possible planned to interview the operating surgeons post-operatively.

4.2 Summary and discussion of findings

A literature review was performed to identify the 'known' factors that may influence PSH development. The literature review identified 138 technical and 50 non-technical factors that were theorised to impact PSH development. Of these, 51 factors were unique and were not identified in the qualitative work.

A second phase, consisting of exploratory work was then undertaken to determine the 'unknown' variations that exist outside of the literature. This identified 150 technical and 64 non-technical factors, 77 of these were not identified in the literature. The mixed qualitative methods also examined the theories held by the healthcare professionals regarding which of these were relevant for PSH prevention. This detail was important for the consensus gaining stage of this research where the origins and theories under pinning the data items supported the consensus process.

The themes from both phases were combined, overlaps and duplicates excluded, and were arranged into a 'long-list' of data items. The long-list of 298 data items was then discussed at a meeting of senior healthcare professionals and trials experts, during which the list was rationalised through consensus to determine the final data items to be collected within the CIPHER study. This resulted in a total of 101 items to be included in the final CRFs.

This methodology systematically identifies and describes the components of a complex intervention and its non-technical influences that may be of interest to collect data on within a cohort study that aims to determine risk factors for a key complication of surgery. This study developed the data items into a manageable number and descriptive form so that they were deemed appropriate and achievable to collect. This approach enabled studies investigating surgical interventions to comprehensively design CRFs to reflect the complexity of the intervention. Making it possible to understand how an intervention was delivered within a study, and within what context, so that appropriate conclusions can be drawn. This work was novel and it has not been possible to identify research that has informed CRFs in this detailed and thorough way before.

A key finding from this research is that unique themes were identified through both phases of data collection. This demonstrates the importance of both examining the literature and investigating the practices/beliefs of healthcare professionals through multiple methods of data collection. Furthermore, by using this methodology the breadth of the data items included in the final CRFs is likely to be far more comprehensive than if the CRFs were designed based on the opinions and interests of the CIPHER study team alone. Considering this during the feasibility stage of the CIPHER study reduces the risk of the CIPHER study missing key variations within stoma formation that may affect PSH development.

Other significant findings include the diversity of techniques and non-technical variations relating to stoma formations. This highlights the complexity of surgical interventions and the need for their development prior to beginning major studies. The broad and often conflicting range of surgical practices/beliefs relating to PSH prevention amongst the healthcare professionals may also represent the lack of clear evidence in the field and/or the lack of healthcare professional awareness of the evidence. This finding demonstrates the need for further research within the field of PSH prevention, a significant gap in the research that the CIPHER study aims to fill.

4.3 Limitations

This section provides a reflection on the limitations and challenges to performing this MSc. Each stage of research will be considered individually.

4.3.1 Literature review

Snowballing methods were used in the literature review because it suited this research's aims. It is especially powerful for identifying high quality sources in obscure locations (63). Snowballing had practical benefits such as yielding a smaller number of results, enabling the reviewer to undertake a more in-depth analysis of the full-text to facilitate the identification of the detailed discourse that this study was interested in. Snowballing was efficient and easy to record in an excel tracker making it transparent and likely to be replicable.

The key limitations to this approach is that it is not a systematic search of all available literature (like an SLR). It is therefore possible that relevant articles were missed as a snowballing strategy favours the identification of well-known, well designed literature as such literature is more likely to be referenced by others. While attempts were made to request all references, some articles identified through snowballing were also not found in their full text version and so could not be fully analysed. Therefore, the articles identified in this study may not represent the full body of existing literature. However, for this project this approach was ideal because it was not necessary to identify all the evidence for a condition, instead this study focused on achieving saturation of themes. Saturation was achieved with the snowballing method and meeting saturation was what initiated cessation of further sampling.

The method used to screen the articles could also be criticised as only one researcher (CM) performed the screening, making it possible that some relevant text was not correctly included. In addition, only a proportion of the included texts were double-coded and the majority of coding was performed by one researcher (CM). This is unlikely to have had a significant impact on the research as the end point of sampling (data saturation) was determined by a second reviewer (NB) who would have identified the emergence of themes should they have been missed by CM.

A final weakness of this method was that CM has no previous experience of PSH or stoma formation therefore CM could have misunderstood highly technical text, potentially leading to missing subtle variations that may impact of PSH development. It is noted that this may also have been a benefit for the analysis, as an attitude of reflexivity is seen as an advantage in qualitative research because if the researcher has no prior knowledge of the research topic they would not be influenced by pre-existing ideas that may affect their interpretation of the data (99, 100).

There were practical challenges associated with using snowballing as the search strategy for this review. This included the identification of the index paper from which to snowball from as there is no published guidance on this. The research team would recommend the use of expert opinion to combat this challenge. Asking experts to recommend a recent, well cited, systematic review that they feel contributes towards answering the research question is likely to be rich in data, contain relevant references and be cited by other articles within the field of interest.

The final challenge included knowing whether to exclude articles by title, abstract or by reading the full-text. The research team approached this challenge by applying simple exclusion criteria (excluding articles not in English and not concerning abdominal stomata) that could be applied easily to titles and abstracts with a low risk of excluding articles that may contain relevant data embedded within the full-text. While this was time-consuming as it meant that many articles required reading the full-text before a decision about including them in the analysis. It was also useful as it was important not to exclude an article too early and risk missing important data within the full-text. The extended time applying the inclusion and exclusion criteria may be offset against the time benefits of snowballing as obtaining references from Google Scholar and its citation tracking service made forward snowballing very efficient.

4.3.2 Qualitative interviews

There are limitations relating to the sampling strategy, data collection and analysis. These are considered below.

4.3.2.1 Sampling

Sampling only took place across two centres which may mean key opinions and processes were omitted. If further centres had been involved this may have provided further information. For example, it may have been beneficial to include centres with a different context, such as within different healthcare systems such as the private setting or a different country. Most surgeons who participated in this study were consultant colorectal surgeons, representing the majority of surgeons performing stoma formation in practice. Additional more junior participants or other types of surgeons undertaking emergency stoma formation may have provided other insights. Furthermore, vascular and gynae oncology surgeons could have also been interviewed to improve the diversity of the sample. Practically this would have been very difficult to achieve, and further sampling was not felt to be practical given the time constraints of the study.

Not all surgeons capable of creating a stoma in each of the centres participated in the mixed qualitative methods research, and as such, not all 'key informants' views in the centres were captured.

4.3.2.2 Data collection

Interviewing healthcare professionals was easy to organise and no healthcare professional that was approached declined an interview. However, CM was unable to find a suitable time to interview four willing surgeons due to their other time commitments (including one gynae oncology surgeon). All interviews were performed face-to-face which is beneficial for the documentation of non-verbal communication and explanatory drawings, which two surgeons performed to enhance CM's understanding of a complex concept.

Timing the interviews and coordinating them with a direct observation as previously discussed in Section 4.3 was a challenge. In optimal conditions interviews would be performed following an observation of stoma formation, to enable better verbal exploration of the observation and triangulation of findings. However, in the absence of an observable stoma formation an interview was performed in isolation. When observations were performed it was not always possible to interview the surgeons immediately following the procedure for various practical reasons, including the surgeon needing a break, the urgency of the next surgical procedure on the list, or additional commitments such as ward patients and administrative responsibilities. Where possible interviews were performed with the operating surgeon after the surgery, however this could be days following the observation. Although, this delay may have meant the surgeon and researcher forgot details of the surgery, it provided the research team (CM and NB) with an opportunity to review the observation data and identify new lines of enquiry and update the topic and observation guide accordingly.

Finally, in keeping with the aforementioned challenges of the time constraints of this study, it was difficult to relate all of the observed and discussed variations of surgical practices back to risk of PSH formation. This limited the research team's ability to explore the importance and priority of capturing these practices in CRFs. The complexities and intricacies of the steps involved in the surgical procedure often led to detailed explanations in the interviews, to the extent where it was not always practical to relate all topics back to PSH formation within the timescale of the interview (or without disrupting the flow of discussion). This casts some doubt over whether true saturation was achieved in relation to surgeons' beliefs. Furthermore, claims of saturation are difficult in this study, which sought to identify and capture as many examples of 'variation' in surgical practice as possible. As mentioned above, including more trusts/individuals in the sample might have illuminated more examples of variation. However, despite this an element of saturation was achieved as during analysis themes were noted to regularly repeat and toward the end of sampling no new themes or connecting between themes and hierarchies were added to the coding framework.

4.3.3 Non-participant observations of stoma formation

Non-participant observations of stoma formation consisted of a direct observation and digital video data capture.

4.3.3.1 Sampling

Six non-participant observations of stoma formation were performed in two different centres, three in each centre. Observations provided large volumes of data that were analysed simultaneously with the interview data. Limitations to this work include the small sample size (n=6) and the limited diversity of the sample. The surgeons observed were six different senior colorectal surgeons: no other specialties were successfully recruited to the observations, as they did not regularly perform stoma formation within working hours and had none scheduled when data collection was proceeding. The context of the stoma formation varied with four different indications for surgery and one emergency procedure. However, it could be considered a limitation that the observations were only performed in two centres. Despite these limitations sampling did not stop until data saturation was met and further observations were therefore not required in these particular centres to add further to the data.

4.3.3.2 Data collection and analysis

Direct observation

The theatre environment is very busy. This sometimes made it difficult for CM to focus on observation of the procedure alone. CM's view was often obstructed, and thus she needed to move to improve her view. This resulted in CM missing some key steps in the stoma formation. The research team managed this limitation by additionally performing digital video data capture which was transcribed by two researchers independently. By video-recording the procedure from a different angle and having two researchers independently transcribe the digital video data capture, variations missed by CM in the direct observation would have been reduced, limiting the impact of this on the results. Other steps that could have been taken to potentially improve the documentation of the observation further could be having an additional researcher in the operating theatre performing the observations and audio-recording the event or the researcher herself scrubbing and directly assisting the operating surgeon.

In addition to the limitations of observing the procedure, it was also very difficult to hear what the theatre team were saying to each other, and hard to observe facial expressions through the theatre masks worn by some of the team members.

Digital video data capture

Arranging for video recording within the trusts required engaging with the local medical imaging departments, who both had differing policies. One trust allowed the research team to borrow a trust approved video recorder to perform the digital video data capture and allowed anyone with the appropriate level of access to theatres to manage the video recorder. With links to the local medical school the local PI was able to easily identify and recruit the assistance of medical student CJ to operate the video recorder.

The other trust required the digital video data capture to be performed on a trust approved video recorder managed by AS, a member of the medical imaging department. The latter required a lot of coordination with AS because not all of the operation needed to be recorded and AS has additional responsibilities that required her to be elsewhere for the full duration of the operation. Timing the video recording was therefore a challenge that had the potential to inhibit digital video data capture of the stoma formation. Fortunately, this did not affect the digital video data capture within this research, however, this will likely be an issue for future observations. The identity and availability of a video recorder manager should be a consideration for future digital video data capture.

Another limitation to the digital video data capture was that the quality of the recordings varied and not all steps were visible. This was often due to video recorder positioning amongst the theatre equipment, ensuring that the recorder did not touch the sterile field, as well as the arm position of the surgeon and/or surgeon assistant. Intra-abdominal components of the surgery were also difficult to capture, due to the camera angle, which may have meant that intra-abdominal variations in technique were missed. A strategy for future observations would be to employ two cameras with one preferably over-head. The possibility of an overhead camera was explored as well as the lead surgeon wearing a ‘Go-Pro’ camera on their head, however both options were infeasible due to costs and local trust policies.

A further potential limitation was the documentation of the digital video data capture. Some of the videos were very long as stoma formation was not always performed in its entirety in one stage. Without surgeon instruction, it was not clear when they were going to commence or recommence part of the stoma formation. This may have led to steps being missed by both the digital video data capture and the transcriber. The detailed account written by CM following each direct observation, based on the observation schedule field notes, was helpful for clarifying elements of the surgery that were performed out of sight of the video recorder (e.g. the product name on the label of the mesh packaging). The detailed accounts were only available to CM when performing the documentation and not NB. This may have been a benefit as NB's documentation would not have been led by CM's interpretation of the stoma formation.

4.3.4 Amalgamation of literature review and mixed qualitative methods

Researchers NB and CM collaboratively amalgamated the technical and non-technical variations of PSH formation from the literature and mixed qualitative methods work and created data items. Some of the data items overlapped with each other (e.g. 'tunnelling of the intestine', 'closure of the lateral space', and 'extraperitoneal stoma formation') yet they all have subtle differences. Challenges associated with this step include formatting the themes into data items that use the correct technical terminology and are understood by healthcare professionals. This took multiple iterations and it was essential to have an experienced surgeon involved in this stage of the research (discussed further in Section 4.4.3).

4.3.5 Consensus methods

The consensus meeting consisted of five colorectal specialists (four consultants and one registrar) as well as one professor of surgery (a consultant non-colorectal surgeon) and one health science professor (BR). The meeting was chaired by NS a senior colorectal surgeon who is also the CI for the main CIPHER cohort study. During this meeting, there was the potential for power imbalances which may have affected the consensus process. For example, the non-colorectal surgeons may have felt reluctant to disagree or offer alternative suggestions. The research team also noted that the chair of the meeting often offered their views and opinions first when discussing a new data item. While this was helpful and facilitated the flow of the discussion the group may have felt reluctant to disagree with the chair. When attempting to ascertain whether consensus had been met regarding categorisation of the data item, the chair asked the panel for agreement and specifically requested that any panellist who disagreed speak up. While efficient, this approach to determining consensus has its limitations as some may have privately dissented but did not say so to avoid confrontation or disruption to the meeting. The participation of two academic attendees was considered to improve the balance of the meeting. The health sciences professor often challenged the surgical participants and provided advice on the feasibility and usefulness of collecting some of the items. This provided a sometimes more realistic alternative view. An example of this comes from the data item concerning measurement of how much 'tension' the stoma is created under. While the surgeons felt that this was an important factor to measure, the health sciences professor advised that this would be impossible to measure as there are currently no tools to measure this or an accepted value for what is considered sufficient or insufficient tension. Considerations such as this highlight potential areas for future research.

A further limitation was likely to be the selection of participants. Notably, the stoma nurses were not represented at the consensus meeting, who may have prioritised the data items differently compared to their surgeon colleagues. In addition, all consensus meeting participants were from the UK and all were from hospitals in the South of the country which could have introduced bias. However, all surgical participants were deemed to be experts and therefore likely to have extensive knowledge and are likely to be representative of their colleagues.

Another recognised limitation to employing consensus methods is the accuracy of the results. As Jones et al, describe "The existence of a consensus does not mean that the "correct" answer has been found—there is the danger of deriving collective ignorance rather than wisdom" (102). This is an unavoidable limitation to consensus methods, however the presence of the researchers (NB and CM) at the consensus meeting allowed for them to describe how each item in the long-list was obtained and demonstrate its potential significance to PSH. This helped the consensus meeting to remain grounded in the original data.

4.3.6 General limitations

The time taken to develop the CRFs in detail may also be considered a limitation of this work. While meaningful, this research was performed with funding and with adequate time prior to the start of the CIPHER study so that it could inform the study documents, which needed to be completed before the CIPHER study's ethics submission. Performing this research could be considered a luxury of time and funding that many other studies would not be able to support. However, this MSc has demonstrated that future studies may accomplish this by building in a phase of feasibility work into their grant applications.

A further limitation to this research is that it assumes that stoma formation is a stable procedure and unlikely to evolve during the duration of the CIPHER study. To combat this the research team has built in an 'other' option into the CRFs, providing participating surgeons with the opportunity to report upon new techniques that they have used or discovered.

4.4 Impact of the researcher

As described in section 2.4.10, this research was performed by CM, a junior doctor. It is possible that CM's pre-conceptions and existing clinical knowledge may have influenced the content and analysis of the semi-structured interviews as well as influenced the content and interpretation of the non-participant observations. The impact of CM on the mixed methods qualitative work has been considered below.

4.4.1 Interviews

The semi-structured interviews were solely performed by CM. All the healthcare professionals interviewed were senior clinicians with a wealth of experience. CM's junior clinical experience was limited in the surgical field and exposure to stoma formation was restricted to what she had read within the literature review. While it can be beneficial for the researcher not to hold pre-existing ideas surrounding the research question, the familiarity with concepts and surgical terminology enabled CM to interact with the healthcare professions naturally. This enhanced the flow of conversation and consequently may have improved the richness of the data. CM felt comfortable asking for clarification and introducing new questions into the conversation. The interviewees may have also felt that CM's clinical experience improved their ability to communicate complex concepts and therefore did not simplify their theories for a more lay understanding.

Additionally, CM's clinical background will have had an impact of the categorisation of phenomena during analysis. This may have helped CM to appreciate the subtleties within the data that a person without clinical experience may not have been able to identify. Although it is possible that CM may have introduced her own pre-conceptions into coding process. However, LR who is not a clinician double-coded a proportion of interview transcripts which would have reduced the impact of CM's medical knowledge.

4.4.2 Non-participant observation

Direct observation

Having previous experience within the theatre setting may have been beneficial to CM's immersion into the theatre environment. This is because CM did not feel as conspicuous or perhaps as unwelcome or burdensome as a researcher without clinical experience might feel. Furthermore, CM was not adversely affected by the scenes of surgery, which is a consideration if performing non-participant observation with non-clinical researchers in the context of the operating theatre.

CM made attempts to be inconspicuous as possible, by reducing her interaction with the theatre team. Despite this the theatre team were aware of her and the video-recorder manager's presence, often directing questions at her and the video recorder manager to make sure that elements of the surgery that they felt were of interest were captured. At times this was a useful device as CM was able to alert the video recorder manager of impending steps of interest. Introducing the theatre staff to the concept of non-participant observation where they are to ignore the presence of the researcher as much as possible, may be beneficial to future applications of this research.

Digital video data capture

The visual nature of the digital video data capture made it a challenge to document. The two independent researchers (NB and CM) were required to watch and re-watch the digital video data capture with frequent re-winding and pausing, to document the steps in sufficient detail. This complexity meant that the step by step documentation created by NB and CM for each of the digital video data capture videos was likely to be influenced by their interpretation of the data. NB's surgical experience was highly beneficial for documenting anatomical positioning, equipment and instrument terminology and understanding certain movements, such as interrupted suturing. Without prior knowledge, it would be difficult for this research to adequately describe the surgical steps within the observations in sufficient detail.

4.4.3 Amalgamation of literature review and mixed qualitative methods

Surgical experience was also essential for the development of data items and the creation of a list that was suitable for consensus meeting and subsequent CRF development. Without the surgical experience of NB, and less so CM, descriptions of the surgical steps and relevant clinical factors would be inadequate for data collection within the CIPHER study. However, this has the potential to affect how the results of this study were grounded in the data. Both NB and CM were conscious of this risk and sought to minimise it by referring back to the verbatim text derived from the transcriptions within NVivo software throughout this process.

4.5 Critical assessment

4.5.1 Quality of this MSc

In the previous section this MSc discussed the limitations of this research. This section will describe how these limitations may have impacted the quality of the results. This critique has been divided into four sections, reflecting the qualitative approach that this research has taken. Consequently, instead of using terms such as validity and reliability this section adopts Lincoln and Guba's approach to appraisal, credibility, transferability, dependability and confirmability (117).

4.5.1.1 Credibility

Credibility within the context of this study can be considered an appraisal of how accurately the researcher has portrayed the ideas and practices of the participants. Researchers relying on interview methods in isolation can never be fully sure that their findings convey the perspectives of participants (118). There is the potential for participants to be dishonest or omit information from the interview. This could have been an issue within this research as healthcare professionals may have felt the desire to provide more professionally acceptable answers that are in line with current surgical dogma and popular opinion of the optimal techniques of stoma formation. A benefit to performing the observations of stoma formation is that the interview data may be triangulated with data from the non-participant observation to test and further explore the complexity of stoma formation. This helped the researchers determine if there was a difference between what surgeons say they do and what they do.

CM used additional methods to improve the credibility of interview findings. The first was using open-ended questions. This was often possible when introducing a new conversation topic, however as exploration of a theme developed within the interviews CM would often move to more direct questioning. The second method used was 'member-checking' whereby CM would repeat what she had understood back to the healthcare professionals to check her interpretation. This practice reduced the risk of CM fitting the interview data into preconceived frameworks (119). Finally, this MSc presented the findings using verbatim quotes to help the reader to make judgements about whether the final themes are true to participants' accounts.

Efforts were also made by the research team to double-code a proportion of the included articles in the literature review and some of the initial interviews. This was done to examine coding strategies and data interpretation. LR double-coded a sample of the literature and NB tested the end point through double-coding. LR also double-coded the initial semi-structured interviews. Additionally, NB and CM both independently created the step by step documentations of the digital video data capture and NB did not have access to CM's detailed account of the observation during this process.

4.5.1.2 Transferability

Transferability concerns how applicable the results are to other contexts. While theoretically this is a difficult concept for qualitative research, where the research findings are bound to the specific group or setting studied, efforts have been made to enhance this MSc's transferability. The sampling and characteristics of the participants are this study's biggest limitation. While this research endeavoured to achieve a diverse sample, as previously discussed, the sample was taken from only two centres and favoured colorectal surgeons. This study's sampling strategy may also have favoured the selection of more research inclined healthcare professionals with strong opinions on PSH prevention. However, three non-colorectal surgeons and three stoma nurses were successfully interviewed, none of whom form stomas routinely, reducing the impact that opportunistic sampling may have had on transferability. The observations were all electively formed stoma formations, bar one, and all were created by colorectal surgeons. While this reflects natural practice as the majority of stomas are formed in this manner, it does raise an issue for transferability. Efforts have been made to clearly describe the research setting, participants and the impact of the researcher on this work to improve transparency and help readers of this research determine the extent to which the findings are transferable to other contexts.

4.5.1.3 Dependability

Dependability makes an assessment of whether the results of this study could be replicated if the work was repeated by another researcher. Again, this is a complex idea within qualitative research, as phenomenon can change over time (120). Having produced a detailed account of the methods used in this MSc, the research team have increased this study's dependability. This should be sufficient for the study to be repeated in the future.

4.5.1.4 Confirmability

Confirmability seeks to assess the extent of which the findings are grounded in the data and not a result of the researchers' influences (121). To improve this study's confirmability the research team performed a number of techniques already discussed. Such as triangulation, double-coding, double independent documentation of the digital video data capture, and an additional researcher reviewed the coding framework to contribute towards ensuring the study findings are grounded in the data. Additionally, CM made efforts to maintain a reflexive practice. CM was aware of the potential impact her clinical experience might have on her conduct during both data collection and interpretation of results. By acknowledging this CM reduced the risk of it occurring. The involvement of LR, a non-clinically trained researcher with a wealth of experience in qualitative research, also improved this reflexivity of this research.

4.5.2 Strategies to improve this research

This MSc has previously listed the limitations to this study and described how the limitations impacted on the quality of the results. The main limitation to this work is considered to be the sample size of participants interviewed and observed during the mixed qualitative methods research. It is recommended that future studies perform mixed qualitative methods work in more centres in different regions of the UK and consider expanding to international centres. Other improvements would be to recruit more emergency stoma formation and stoma formations performed by other specialties for non-participant observation.

4.5.3 Further research

This work leads directly into the CIPHER study. During the CIPHER study participant data will be collected to answer the data items in the CRFs that this research has designed. The CIPHER study data will determine which of the themes identified during this work are relevant to PSH prevention. The results of the CIPHER study will in turn lead to the identification of further research priorities and provide an evidence base for future RCT design and funding.

The CIPHER study has now opened in 23 centres and 41 patients have been recruited. The quality of data collection so far is strong with 37 electronic CRFs completed. Of the remaining, one is awaiting surgery and three are missing from the same centre. This may be suggestive of a local issue that may be unrelated to the quality of the electronic CRF.

As briefly mentioned in Section 4.3.5, an additional area for future research identified by this work could be further investigation of the factors that were consider important to PSH prevention but currently have no methods or standardised parameters for their measurement, such as assessment of stoma tension.

4.5.3.1 Applicability to other studies

This research developed a methodology for future studies to scientifically identify and develop data items for CRF construction., providing a meaningful way for research teams to decide what information to collect within their study.

This methodology can be to optimise documentation of research delivery of a complex intervention. For observational studies this can help determine which key elements of a complex intervention are prognostically important for outcomes. For RCTs it can be used to ensure that the intervention was delivered as intended and/or to understand variations in results. These methods can also make future research more relevant to clinicians because it will allow them to compare and contrast their own surgical practices and ideas about what components of an intervention are important. Further applications of this methodology include its potential to benefit RCTs. Both for RCTs and cohort studies this methodology may be used to help provide an evidence base which could be used for secondary analyses. Documentation of the components of interventions would allow advanced analyses to be undertaken to determine which elements of a complex intervention are ‘active’ and which are most importantly linked to key outcomes. Another possible use of this research is to create standard CRFs for certain surgical procedures (core CRFs) and these could be used across studies with additional study specific items if required. This would improve data synthesis and shared learning from trials.

CHAPTER 5. CONCLUSION

Surgical interventions are complex; consequently, designing and conducting surgical research is very challenging needing to account for intervention complexity and delivery. Under the subject of PSH prevention, this MSc examined the complexity of stoma formation and the challenges of conducting surgical research through the development of CRFs for a large cohort study. It utilised and built on the methodology developed by Blencowe et al (44) for understanding a complex surgical intervention as feasibility work to inform the design of RCTs. Conclusions which can be drawn from this enhanced methodological approach are discussed below in chronological order of how the study was completed.

Data collection through both a literature review and mixed qualitative methods were invaluable to the success of the study. With the aim to collect a long-list of all potential variations of interest to the CIPHER study, gathering information from many participants and methods of data collection was essential. This was proven in the outcomes of this study, as large number of unique themes were identified through each stage. For example, the literature review identified 51 themes which were not identified in the qualitative methods work. This was an additional stage to Blencowe et al's methodology which would be recommended for future similar work. In the same way, the mixed qualitative methods alone helped to identify a further 77 unique themes.

This combined approach of investigating the literature and 'real-life' scenarios was considered crucial to understanding the complexity of stoma formation. These methods also highlighted the diversity of surgical techniques practiced in stoma formation and conflicting opinions of healthcare professionals on PSH prevention. This inconsistency emphasised the complexity of stoma formation, the importance of using multiple methods of data collection and demonstrated the lack of clear and conclusive evidence on PSH prevention available.

The roles and experience of the research team was considered an asset to the outcomes of the study. Firstly, having a mixture of clinical experience was very beneficial for the non-participant observations. With the lead researcher's junior clinical training, it allowed them to immerse themselves comfortably within the surgical environment and get the most out of the data collection exercise. This junior training combined with the other researcher's in-depth surgical experience was beneficial for scrutinising the data on many levels and also developing the structure and language of the themes in a way which was well understood within the surgical community. The addition of an experienced qualitative researcher when analysing the data further enhanced the rigor of this research and maintained its grounding within the data.

Development of the CRFs through this comprehensive data collection methodology is deemed worthwhile and was demonstrated at the consensus meeting. Having a long-list that was grounded in the original data, the origins of which could be explained by the researchers, was fundamental to the consensus meeting's decision-making process. It ensured that a comprehensive list supported by the research findings was considered instead of the meeting attendees providing a sample of healthcare professionals views.

This body of work leads directly on to the CIPHER study where the value that this MSc has contributed will be monitored. The CIPHER study will collect participant information for each of the data items included in the final CRFs. It is believed the completeness of the final CRFs will be of great value in the CIPHER study to determine which of the technical and non-technical components of stoma formation are prognostically important for the development of a PSH. The conclusions from the CIPHER study will go on to influence future research priorities and improve the evidence base available to practicing surgeons on this highly complex subject.

This MSc described how feasibility work can be performed to develop an understanding of a complex intervention and inform the design of CRFs to enable data collection on natural, un-prescribed surgical practice. Additionally, this work demonstrates how understanding the heterogeneity of a complex interventions is also beneficial to cohort study design when the aim of the study is to determine how variations of surgical technique and non-technical variations (e.g. contextual factors, concomitant interventions, surgeon and patient related factors) may act as risk factors for complications or affect outcomes. Developing comprehensive CRFs that are systematically and transparently designed may help reduce criticism of the future studies and may also improve buy-in from surgeons both seeking to participate as well as those reading the results.

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Appendix 1

Observation schedule V2.0 (final version)

Observation schedule – CIPHER PHASE A

V2.0 17/8/16
Time patient arrived: Finish time:
People in room: Patient factors:

Time/Phase of operation	Surgeons	Other
Context of stoma formation Emergency / planned Open/Laparoscopic/Mixed Indication for procedure Patient factors e.g. ASA Pre-stoma formation Bowel excised Length of bowel mobilised TECHNICAL Dialogue, actions What surgeon looking at Errors? Progress Instruments CONTEXT Patient factors Tiredness, stress Training Equipment Distractions/interruptions Noise or music		

Observation schedule

Time/Phase of operation	Surgeons	Others
Skin incision Location Presence and use of pre-marked site Size and shape of skin incision Diathermy or scalpel Adipose, divided or excised Use of incision as port site (if lap) TECHNICAL Dialogue, actions What surgeon looking at Errors? Progress Instruments CONTEXT Patient factors Tiredness, stress Training Equipment Distractions/interruptions Noise or music		

Observation schedule

Time/Phase of operation	Surgeons	Others
Abdominal wall incision Location of incision Anterior sheath incision shape and size, instruments used. Rectus/external oblique divided or incision. Posterior rectus sheath incision shape and size, instruments used. Dilatation of trephine (manual, instrument, absent) TECHNICAL Dialogue, actions What surgeon looking at Errors? Progress Instruments CONTEXT Patient factors Tiredness, stress Training Equipment Distractions/interruptions Noise or music		

Observation schedule

Time/Phase of operation	Surgeons	Others
Mesh Yes/no Size, shape, composition of mesh Antibiotics Position of mesh Technique –keyhole, modified Sugarbaker Method and material used to secure the mesh TECHNICAL Dialogue, actions What surgeon looking at Errors? Progress Instruments CONTEXT Patient factors Tiredness, stress Training Equipment Distractions/interruptions Noise or music		

Observation schedule

Time/Phase of operation	Surgeons	Others
Bringing the bowel out Route of bowel How is bowel bought out (Manual, instrumental) Ease of bowel manipulation Adjustments Further incision/dilatation Securing the bowel Closure of lateral spaces TECHNICAL Dialogue, actions What surgeon looking at Errors? Progress Instruments CONTEXT Patient factors Tiredness, stress Training Equipment Distractions/interruptions Noise or music		

Observation schedule

Time/Phase of operation	Surgeons	Anaesthetists	Nurses
Other TECHNICAL Dialogue, actions What surgeon looking at Errors? Progress Flicking back and forward Instruments CONTEXT Patient factors Tiredness, stress Training Equipment Distractions/interruptions Noise or music			

Appendix 2

Interview topic guide CIPHER Study Part 1: Healthcare Professional topic guide V 3.0 (17th August 2016) final version

PART 1: PROVISIONAL INTERVIEW TOPIC GUIDE - Healthcare professionals' perspective on the surgeon's technique of stoma formation and on surgical risk factors for parastomal hernia (PSH) development

<u>Opening</u>

Interviewer will re-iterate study information, answer any questions, and take written consent.

(Check consent signed, recorder ON)

<u>Background, interviewee details and ice-breaker</u>

This is an interview performed on ….. at…… Study number……

- Details of interviewee's current position and role, working history in clinical role, experience etc.
  - Define specialty experience i.e. specialist colo-rectal surgeon, general surgeon and grade of surgical experience, how often they perform stoma formations.

Stoma formation

- Could you describe - from start to finish - the stoma formation you performed/your usual approach to stoma formation?
  - Prompt: permanent end stoma.
  - Probe: Size, shape and location of incision, use of prophylactic mesh etc.
  - Probe: IS there any difference in how you perform an Open/Laparoscopic stoma formation, Ileostomy, or loop colostomy.

- Can you explain the mechanism of Parastomal hernias formation to me please?
- In your opinion, which surgical techniques are associated with PSH formation?
    - Prompt: Trephine (size, shape, location), mesh, closure of lateral space
    - Probe: Why is that? As informed by the literature.
- Are there any factors that affect your choice of surgical technique
    - Prompt: Indication of surgery, patient factors such as obesity
    - Probe: As informed by the literature
- Are there any other non-technical factors related to the operation that may affect PSH development?
    - Prompt: Such as planned or unplanned surgery, grade and speciality of surgeon, time of operation, indication of operation etc.
    - Probe: As informed by the literature
- Are there any patient-related factors that you think might affect PSH development?
    - Prompt: obesity, age, co-morbidities, etc.
- Are there any pre-operative or post-operative factors that you think are important?
    - Prompt: Such as pre-operative factors e.g. as stoma nurse marking & post-operative factors e.g. support garments, prevention programmes.
    - Probe: As informed by the literature
- Is there anything else that you think is important in preventing PSH that we haven't discussed?
    - Probe: Why do you think this?

Questions derived from non-participant observation

- "I noticed you did [observation]. I am interested in understanding why you did that, can you explain it a bit more to me?"
- Some surgeons do X (mesh/trephine etc.). I'm interested in understanding why you didn't do that"

- “What do you think the result of [observation] will be?”

Closing

Interviewer checks consent taken, checks understanding of any outstanding points, answers further questions, and checks to see if interviewee would like to receive a summary of findings.

(Thank you, Recorder OFF)

Comments:

Appendix 3

Interview topic guide CIPHER Study Part 1: Healthcare Professional topic guide V 1.0 (22nd March 2016)

PART 1: PROVISIONAL INTERVIEW TOPIC GUIDE - Healthcare professionals' perspective on the surgeon's technique of stoma formation and on surgical risk factors for parastomal hernia (PSH) development

<u>Opening</u>

Interviewer will re-iterate study information, answer any questions, and take written consent. **(Check consent signed, recorder ON)**

<u>Background, interviewee details and ice-breaker</u>

- Details of interviewee's current position and role, working history in clinical role, experience etc.
    - Define specialty experience i.e. specialist colo-rectal surgeon, general surgeon and grade of surgical experience, how often they perform stoma formations.

Stoma formation

- Could you describe - from start to finish - the stoma formation you performed/your usual approach to stoma formation? *(Prompt: Size, shape and location of incision, use of prophylactic mesh etc.)*
- Can you tell me what you understand about Parastomal hernia formation?
- In your opinion, which surgical techniques are associated PSH formation?
- Prompt: trephine (size, shape, location), mesh, etc – informed from the literature categories

- Probe: Why is that?
- Are there any factors that affect your choice of surgical technique (Prompt: indication of surgery, patient factors such as obesity- draw on things you've found in the literature etc)
- When you review a new stoma, what would make you think it was likely or unlikely to be at risk of a PSH?
- Do you think whether the procedure was performed as an emergency makes a difference to the risk of PSH formation? If so, why? What, specifically, is it about the emergency context that impacts risk of PSH formation?
- Do you think whether the procedure was performed by a specialist or general surgeon makes a difference?
- Do you think whether the procedure was performed by a senior or junior surgeon makes a difference?
- Is there anything else you think that's important in preventing PSH that we haven't discussed?

Questions derived from non-participant observation

- "I noticed you did [observation]. I am interested in understanding why you did that, can you explain it a bit more to me?"
- Some surgeons do X (mesh/trephine etc). I'm interested in understanding why you didn't do that"
- "What do you think the result of [observation] will be?"

Closing

Interviewer checks consent taken, checks understanding of any outstanding points, answers further questions, and checks to see if interviewee would like to receive a summary of findings.

(Thank you, Recorder OFF)

Comments:

Appendix 4

Interview topic guide V2.0 CIPHER Study Part 1: Healthcare Professional topic guide V2.0 (5th July 2016)

PART 1: PROVISIONAL INTERVIEW TOPIC GUIDE - Healthcare professionals' perspective on the surgeon's technique of stoma formation and on surgical risk factors for parastomal hernia (PSH) development

<u>Opening</u>

Interviewer will re-iterate study information, answer any questions, and take written consent.

(Check consent signed, recorder ON)

<u>Background, interviewee details and ice-breaker</u>

- Details of interviewee's current position and role, working history in clinical role, experience etc.
    - Define specialty experience i.e. specialist colo-rectal surgeon, general surgeon and grade of surgical experience, how often they perform stoma formations.

Stoma formation

- Could you describe - from start to finish - the stoma formation you performed/your usual approach to stoma formation?
    - Prompt: Size, shape and location of incision, use of prophylactic mesh etc.
- Can you tell me what you understand about Parastomal hernia formation?
- In your opinion, which surgical techniques are associated with PSH formation?

- Prompt: Trephine (size, shape, location), mesh, etc – informed from the literature categories
- Probe: Why is that?

- Are there any factors that affect your choice of surgical technique
    - Prompt: Indication of surgery, patient factors such as obesity- draw on things found in the literature etc.
- When you review a new stoma, what would make you think it was likely or unlikely to be at risk of a PSH?
    - Pilot this question
- Are there any factors surrounding the operation that may affect PSH development?
    - Prompt: Such as planned or unplanned surgery, grade and speciality of surgeon, time of operation, indication of operation etc.
    - Probe: As informed by the literature
-
- Are there any patient-related factors that you think might affect PSH development?
    - Prompt: obesity, age, co-morbidities, etc
    - Probe: Why do you think this?
- Is there anything else that you think is important in preventing PSH that we haven't discussed?
    - Prompt: Are there any factors other than the stoma formation itself that you think are important? E.g. non-technical factors, such as pre-operative factors, post-operative factors, patient factors, and why)
    - Probe: As informed by the literature

Questions derived from non-participant observation

- "I noticed you did [observation]. I am interested in understanding why you did that, can you explain it a bit more to me?"
- Some surgeons do X (mesh/trephine etc.). I'm interested in understanding why you didn't do that"

- “What do you think the result of [observation] will be?”

Closing

Interviewer checks consent taken, checks understanding of any outstanding points, answers further questions, and checks to see if interviewee would like to receive a summary of findings.

(Thank you, Recorder OFF)

Comments:

Appendix 5 List of articles included in the literature review analysis

Included article reference	Index paper reference	Identified through forward or backward snowballing
Pearl RK. Parastomal hernias. World journal of surgery. 1989 Sep 1;13(5):569-72.	Shabbir J, Chaudhary BN, Dawson R. A systematic review on the use of prophylactic mesh during primary stoma formation to prevent parastomal hernia formation. Colorectal Disease. 2012 Aug 1;14(8):931-6.	Forward
Helgstrand F, Gögenur I, Rosenberg J. Prevention of parastomal hernia by the placement of a mesh at the primary operation. Hernia. 2008 Dec 1;12(6):577-82.		Forward
Carne PW, Robertson GM, Frizelle FA. Parastomal hernia.Br J Surg 2003; 90: 784–93.		Forward
Hammond TM, Huang A, Prosser K, Frye JN, Williams NS.Parastomal hernia prevention using a novel collagen implant:a randomised controlled phase 1 study. Hernia 2008; 12:475–81.		Forward
Israelsson LA. Preventing and treating parastomal hernia.World J Surg 2005; 29: 1086–9.		Forward
Schafer M. Preventing parastomal hernia with a prosthetic mesh: a five year follow up of a randomised study. World J Surg 2009; 33: 122–3.		Forward
Serra-Aracil X, Bombardo-Junca J, Moreno-Matias J et al. Randomized, controlled, prospective trial of the use of a mesh to prevent parastomal hernia. Ann Surg 2009; 249:583–7.		Forward
Jansen PL, Mertens Pr P, Klinge U, Schumpelick V. The biology of hernia formation. Surgery 2004; 136: 1–4.		Forward
Rosin JD, Bonardi RA. Paracolostomy hernia repair with Marlex mesh: a new technique. Dis Colon Rectum 1977; 20: 299–302.		Forward
Hansson BM, de Hingh IH, Bleichrodt RP. Laparoscopic parastomal hernia repair is feasible and safe: early results of a prospective clinical study including 55 consecutive patients. Surg Endosc 2007; 21: 989–93.		Forward
Vijayasekar C, Marimuthu K, Jadhav V, Mathew G. Parastomal hernia: is prevention better than cure? Use of preperitoneal polypropylene mesh at the time of stoma formation Tech Coloproctol 2008; 12: 309–13.		Forward
Bayer I, Kyzer S, Chaimoff CH. A new approach to primary strengthening of colostomy with Marlex mesh to prevent paracolostomy hernia. Surgery, gynecology & obstetrics. 1986 Dec;163(6):579-80.		Forward

Included article reference	Index paper reference	Identified through forward or backward snowballing
Gogenur I, Mortensen J, Harvald T, Rosenberg J, Fischer A. Prevention of parastomal hernia by placement of a polypropylene mesh at the primary operation. Dis Colon Rectum 2006; 49: 1131–5.		Forward
Thompson MJ. Parastomal hernia: incidence, prevention and treatment strategies. Br J Nurs 2008; 17: S16.S18–20		Forward
Marimuthu K, Vijayasekar C, Ghosh D, Mathew G. Prevention of parastomal hernia using preperitoneal mesh: a prospective observational study. Colorectal Disease. 2006 Oct 1;8(8):672-5.		Forward
Janes A, Cengiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh: a 5-year follow-up of a randomized study. World J Surg 2009; 33: 118–21. discussion 122–3		Forward
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Appendix 6: Results of the mixed qualitative methods research continued

1. Technical variations

1.1. Surgical approach to stoma formation

During the interviews, the surgeons reported two different surgical approaches to stoma formation when discussing their practices in interviews: laparoscopic and open surgery. However, the non-participant observations showed that a third method was also performed: conversion from laparoscopic to open, a mixed procedure. This was apparent is observation BRI0034 when the surgeon converted a laparoscopic procedure to open due to difficult access. Some surgeons and stoma nurses expressed that there is likely to be a difference between PSH rates depending on whether the approach was laparoscopic or open.

> *"I would favour using a laparoscopic technique if that was technically possible. The reason being that you can actually confirm the anatomy so you can perform an end colostomy, which I think reduces the risk of parastomal formation and the other complications such as prolapse and retraction. You can actually mobilise the colon to bring it up to the abdominal wall.". [HCP: BRI0022, Surgeon Lower GI, RDE]*

> *"There is talk, that maybe sometimes laparoscopic surgery they end up with more hernias, but to me I think it's when they've had a full-blown laparotomy and then they have a stoma form. I think they're probably more at risk because they've got double… They appear to have weaker muscles, don't they?" [HCP: BRI0003, Stoma Nurse, BRI]*

As demonstrated below, HCPs had different views about which technique is optimal for PSH prevention.

> *"One of the things that I've thought is important is you want the stoma to come through the strongest part of the abdominal wall. Particularly if the patient's had laparoscopic surgery. The reason being they've got fewer intra-abdominal adhesions, because with laparoscopic surgery there's less bowel handling. [The] small bowel is more mobile. In an era with complex open surgery, and dense intra-abdominal adhesions, parastomal hernias were possibly less common, because of the fact that the bowel was not mobile inside the abdomen. Often they ended up with frozen abdomens." [HCP: BRI0023, Surgeon Lower GI, RDE]*

> *"I suspect there's a higher incidence of (PSH in) laparoscopic surgery and, whether that's due to lack of adhesions or because we are delivering specimens through the stoma, there's a little bit of evidence to suggest that." [HCP: BRI0032, Surgeon Lower GI, RDE]*

> *"By doing laparoscopic you make smaller incisions in the sheath and the layers, which has to be important for hernia formation. By doing laparoscopic you do reduce parastomal herniation. Whether mobilising it makes a difference, I think probably mobilising means you are less likely to get retraction or ischaemia with the actual stoma itself. That predisposes to infection and that might increase your hernia rates thinking through logically." [HCP: BRI0022, Surgeon Lower GI, RDE]*

1.2. Type of stoma formed

Some surgeons and stoma nurses reported that the type of stoma formed may be relevant to PSH prevention. Findings from both the interviews and observations indicated that the type of stoma formed could vary considerably, depending on numerous factors, including:

- The section of the bowel used to create the stoma (ileostomy, colostomy)
- How the stoma was secured to the skin (loop, end, double barrelled)
- The intended life-span of the stoma (permanent, temporary)
- Whether the surgeon was converting the stoma from a loop to an end, or creating a trephine stoma.

a) Section of the bowel used to create the stoma

Some surgeons report that they would vary their technique depending on what section of bowel was used to create the stoma. For example, BRI0001 reports that they would make a bigger stoma trephine for a stoma using part of the colon (colostomy) than they would for a stoma that used part of the ileum (ileostomy) to create the stoma. A stoma nurse BRI0002 also felt that there may be a difference and that stoma's using the transverse colon were at greater risk of developing a PSN.

Interviewer: "Would you make your hole larger then if it was a colostomy?"

Respondent: "Yes, slightly bigger, yes, because the bowel is bigger…50p shape is what I've been taught for colon…" [HCP: BRI0001, Surgeon, Upper GI, BRI]

"I'm not really very aware of the surgical techniques. I do know that a transverse colostomy or a transverse stoma is much more likely to prolapse

and herniate. I suppose, I don't know, there are… An end seems less likely; a loop ileostomy seems more likely to get a parastomal hernia than an end ileostomy. I'm trying to think if colostomies seem less likely to get an earlier-on hernia and more likely to get a later-on hernia." [HCP: BRI0002, Stoma Nurse, BRI]

b) How the stoma was secured to the anterior abdominal wall

During the interviews, some surgeons reported that the different methods (end stoma, loop stoma, double barrel stoma) of securing the stoma to anterior abdominal wall may impact of PSH development. Two surgeons BRI009 and BRI0022 felt that this may be because of the larger defect in the abdominal wall needed for a loop or double-barrelled stoma, rather than an end stoma.

"I mean, so if it's a double barrel stoma then it needs to be a bigger defect. That's quite rare to have to do that." [HCP: BRI0009, Surgeon, Upper GI, BRI]

"It does, you can do end stoma rather than a loop. The loop ones I think we tend to have a lot more trouble with prolapse, retraction and herniation because you have to make a bigger cut to bring up the loop of the colon." [HCP: BRI0022, Surgeon, Lower GI, RDE]

"Some people for loop stomas will use a bridge. And I don't know- I mean, I've tried not to, just because I don't like leaving a defect where the bridge is. But I don't know if that will have an impact on the parastomal hernia formation." [HCP: BRI0009, Surgeon, Upper GI, BRI]

c) Temporary or permanent

One of the stoma nurses suspected that there may be a difference in the quality of stoma formation depending on whether the surgeon intended the stoma to be temporary or permanent, and this may have consequences for PSH rates.

> *"I think with a loop ileostomy I'm not sure that perhaps the surgeons, because they think it's going to be a temporary stoma, I wonder – and I don't mean to cast aspersions – whether their priority lies less with hernia prevention than with just facilitating the surgery, getting the stoma up and concentrating more, I suppose, on the anastomosis and all of that and worrying less about… I think, perhaps, more care is taken if they know that the stoma is going to be permanent, but not always." [HCP: BRI0002, Stoma Nurse, BRI]*

d) Trephine stoma

Trephine stomas are where the stoma site is the only abdominal wall incision made by the surgeon. These are usually done as palliative procedures where the surgeon only needs to decompress the bowel rather than excise any pathology. Trephine stomas were theorised to carry an increased risk of PSH formation. BRI002 felt that this may be because of bowel mobility issues or because you need to create a loop stoma and create a larger trephine.

> *"You can't mobilise a colon with a trephine procedure because the hole is that sort of size. Laparoscopically you can easily get some scissors or a hook and go along the left side of the colon and free it up. You can actually assess the anatomy where things are." [HCP: BRI0022, Surgeon, Lower GI, RDE]*

> *Interviewer: "In terms of parastomal hernia formation would you say that a patient was more likely to get one perhaps if they had a trephine open stoma formation than if they had a laparotomy their stoma?"*

Respondent: "Yes, I think they would. I think by the nature of it normally being a loop is a bigger bit of bowel. You need to have a bigger cut in both the anterior sheath and posterior sheath to bring up the big lump of bowel ___ bring the loop" [HCP: BRI0022, Surgeon, Lower GI, RDE]

e) Conversion from loop to end

Participant BRI0023 reported that patients who have had conversions from a loop to an end stoma always develop a PSH.

"The thing is, for those patients who have had loop colostomies formed, who you then have to when you do your definitive surgery convert from a loop sigmoid colostomy to an end sigmoid colostomy, as part of an abdominoperineal excision, those patients are guaranteed to get parastomal hernias… And once you've made a big hole you can't make it smaller again. They will always come back, and they will always have a parastomal hernia. It's always terribly difficult to fix" [HCP: BRI0023, Surgeon, Lower GI, RDE]

1.3. Mobility of the bowel

Surgeons and stoma nurses generally thought that the length of bowel mobilised could influence PSH development. BRI009, BRI0022 and BRI0010 felt that too little mobilisation would result in stoma being formed under tension. Tension on the stoma was felt to be associated with poor outcomes, including increase infections and surgeon being required to work harder to stretch the muscle to accommodate a poorly mobilised bowel length. These surgeons felt that this may contribute to an increased risk in PSH development. BRI0015 felt that too much mobilisation could result in 'floppy bowel' that could herniate up into the abdominal wall defect.

"If they don't free up enough bowel in surgery, that could cause problems, big tension and everything." [HCP: BRI0003, Stoma Nurse, BRI]

Interviewer: "What do you think about the amount of bowel mobilised? Do you think that would make a difference to parastomal hernias?"

Respondent: "Probably. Yes, you're probably right, probably more with stoma prolapse or retraction, rather than parastomal hernias. I suppose if you have a prolapsing stoma, it would widen the defect. I don't know." [HCP: BRI0009, Surgeon, Upper GI, BRI]

"I think probably mobilising means you are less likely to get retraction or ischaemia with the actual stoma itself. That predisposes to infection and that might increase your hernia rates thinking through logically." [HCP: BRI0022, Surgeon, Lower GI, RDE]

"I think of you have enough mobilised bowel, it makes a relatively neat stoma, you don't have to struggle pulling and pushing through that hole, so I think it probably does affect, even though it would be very hard to prove…But if you have a tight length and you're trying to stretch those muscles, trying to pull everything out, you're bound to probably damage more muscles. I think it would be very hard to prove it or try to in a study, whether it makes a difference or not." [HCP: BRI0010, Surgeon, Lower GI, BRI]

"If you've got somebody who's got a large hole but a relatively taught piece of bowel going through it and the hole gets bigger then something can go along the side of it. Alternatively if you've got somebody who's got a large hole and very floppy bowel that can put another loop next to it then." [HCP: BRI0015, Surgeon, Lower GI, RDE]

1.4. Pre-marked stoma site

Typically, a stoma nurse would pre-operatively mark the site on the patient's abdomen where they recommended the stoma be formed. The majority of surgeons mentioned the importance of having the stoma site pre-marked prior to surgery. However, surgeons had differing opinions on the importance of this factor for PSH prevention. It was not clear whether the important element of having the stoma site pre-marked was related to marking the site or the location of where the stoma would be placed:

> *"I would have worked with the specialist nursing team, stoma team, so that they have put some optimal sites on the anterior abdominal wall, and marked preoperatively." [HCP: BRI0018, Surgeon, Hepatobillary, RDE]*

> *Interviewer: "You also mentioned preoperative marking of the stoma site. Do you think that will make a difference to the parastomal hernia rates?"*
>
> *Respondent: "It probably doesn't, it is probably more about having a better site for the patient in terms of a place where they can change it. I suppose sometimes if it is marked in a position that is not ideal for a surgeon it can be more challenging for us. If anything is more challenging you might increase things marginally, but probably not." [HCP: BRI0022, Surgeon, Lower GI, RDE]*

From the non-participant observations, it was noted that there may be multiple sites marked and efforts may be made to preserve the marked site with drawn arrows and sutures.

> *"The stoma site is pre-marked at two sites above and below and left lateral to the umbilicus. Both sites have been tied with a suture." [Observation CM: BRI0014, End colostomy, Laparoscopic, BRI]*

"The consultant surgeon uses babcock grasps skin at pre-marked stoma site" [Observation CM: BRI0033, End Ileostomy, Laparoscopic, RDE]

"Two permanent marker marked sites left and right of the umbilicus with a suture in both. With pen marked arrows on both". [Observation CM:BR0021, End Colostomy, Laparoscopic, RDE]

1.5. Skin preparation with antiseptic

During the non-participant observations, it was noted that the skin had been 'prepped', meaning that it was cleaned with antimicrobial solution (either Iodine or Chlorhexadene):

"The abdomen is prepped with chlorhexadene cleaning solution and sterile drapes are applied." [Observation CM: BRI0014, End colostomy, Laparoscopic, BRI]

"Skin prepped with iodine solution." [Observation CM: BRI0033, End Ileostomy, Laparoscopic, RDE]

1.6. Route of the stoma

During the interviews, it was discussed that a stoma may take a transperitoneal, extraperitoneal (also known as tunnelling the bowel) or oblique route through the abdomen. All surgeons interviewed and observed used a transperitoneal technique.

a) Transperitoneal or extraperitonal

Two surgeons discussed the possibility of using an extraperitoneal technique, one reporting (BRI004) that there may be a difference between PSH rates between transperitoneal and extraperitoneal though they did not describe the mechanism through which a difference may occur. All surgeons felt that this was an outdated technique, and implied that it is not practiced in the UK.

"I would do a trans-peritoneal end colostomy" [HCP: BRI0004, Surgeon, Lower GI, BRI]

"Technical factors associated with parastomal. So, I suppose one thing to address is whether we do this as a trans-peritoneal, or an extra peritoneal approach. So, years ago, in the '60s and '70s, and maybe even more recently, it was quite common for the stomas to be tunnelled, pre-peritoneally, laterally, so essentially what you were doing is you'd have the bowel up laterally against the abdominal wall or the under surface, and then it would come out through the muscles as an extraperitoneal stoma. That may have an impact, I don't know, that's never been subjected to a randomised trial comparing it to the trans-peritoneal approach, where the bowel simply just comes through the abdominal wall without tunnelling it. So I think that's a possible surgical technique factor." [HCP: BRI0004, Surgeon Lower GI, BRI]"

"Some people might mobilise more to facilitate an extraperitoneal routing. I don't do extraperitoneal routes. I don't think I've ever seen anyone do an extraperitoneal route. It's not commonly used in the Western world. It's almost entirely in Asia, as far as I can ascertain. I know there are some people in America who are interested, and then there's been a bit of a resurgence. It's not easy to do in obese populations. The mesentery is too fatty. It's just bloody difficult…I don't think I've ever seen one done." [HCP: BRI0023, Lower GI, RDE]

"I think it was something that was done a long time ago, and it doesn't seem desperately difficult to do, but it's just something, again, I was never brought up as a surgeon doing, so I don't do it." [HCP: BRI0004, Surgeon Lower GI, BRI]

b) Oblique route of the stoma through the abdominal wall

One surgeon (BRI009) discussed the possibility of creating an oblique stoma, that runs obliquely through the abdominal wall to help reduce PSH rates. Though they had not tried it themselves as they believed there may be complications associated with performing an oblique route. A further surgeon (BRI0015), when questioned on this possibility, felt that it would create a large hole in the abdominal wall and would not be successful:

"So, you know, I've thought about displacing the skin and rectus sheath defects in the same way that, you know, your inguinal canal is designed- well, it wasn't designed, but is oblique. And that minimises, theoretically, direct hernias, because you've got- the defects are not overly… But the problem is, I worry about the distortion of the bowels going through, causing it to not open and not enter very well. And having obstructive symptoms. And that's why I've kind of not really explored that." [HCP: BRI0009, Surgeon, Upper GI, BRI]

"The more difficult it is to make a tunnel, the more likely you are to make a bigger hole (and increase the risk of PSH)." [HCP: BRI0015, Surgeon, Lower GI, RDE]

c) Other consideration for route of the stoma

Some surgeons felt that it was important to align the abdominal layers when creating the trephine. This was thought to be important when doing an open procedure. The surgeon BRI0036 felt that while creating a 'kink' by not having good alignment may not cause a PSH in itself, it may cause 'reoperation' which in turn may lead to a higher PSH incidence:

Respondent: "I think it is important that you don't, that you go straight down particularly in a large abdomen if you start deviating off to one side then you can get kinks in the stoma and that's poor function rather than parastomal hernias… now the slim patient you haven't got far to go, but in a large patient if you go off to one side, particularly when you close the abdomen and you've done it up in the retracted position then you can end up with a (unclear) it goes off to the side and I think that can cause some stoma kinking earlier on."

Interviewer: "Do you think it will have an affect on parastomal hernias?"

Respondent: "Hmm not hernias per se no but as soon as you get a complication with a stoma and re-operate on it then I think you've got very high chance of parastomal hernia. So if you get, you know if you've got a kinked stoma it doesn't work very well and you have to re-operate on it." [HCP: BRI0036, Surgeon, Lower GI, BRI]

Both BRI0009 and BRI0036, specifically reported that when creating a stoma they took steps to ensure the abdominal wall layers were aligned, though it was not clear from the interviews whether this was important to PSH prevention:

"Presuming it's done at the time of a laparotomy. So I would put some sort of grasping forceps or clips on the rectus sheath to pull it towards the midline." [HCP: BRI0009, Surgeon, Upper GI, BRI]

"The key thing is that you're not tunnelling, that you're not going off to one side you're going straight down. So that's why you bring the fascia and the skin to the midline, you want to go straight down then langenbecks to find the fascia". [HCP: BRI0036, Surgeon, Lower GI, BRI]

1.7. Skin incision

Numerous variations in surgical technique for the skin incision when creating the stoma trephine.

a) Instrument used to create the skin incision

Our interview cohort reported that the skin incision for the stoma trephine may be performed with either diathermy or scalpel.

> *"Holding the skin edges with some forceps, the surgeon uses diathermy to incise each edge (skin and subcutaneous tissue), thereby turning the cruciate incision into a oval." [Observation NB: BRI0034, End Ileostomy, Converted laparoscopic to open, BRI]*

> *"The surgeon turns the knife 90 degrees and 'shaves through' the skin around the Langenbeck. This makes a circle shaped incision in the skin. They then achieve haemostasis using forceps diathermy." [Observation NB: BRI0021, End Colostomy, Laparoscopic, RDE]*

b) Size and shape of the skin incision

Surgeons described three different sizes for the skin incision in the interviews. All expressed that this was an imprecise, using words such as "ballpark", "about" and "approximately":

> *"I make a circular incision, it's, ballpark figures, maybe around 3cm." [HCP: BRI0004, Surgeon Lower GI, BRI]"*

"I'd make a coin-shaped incision, about a 50p-size/shaped incision, going straight across with a knife, stop the bleeding." [HCP: BRI0001, Surgeon, Upper GI, BRI]

"Excise a disc of skin approximately 2cm in diameter." [HCP: BRI0023, Lower GI, RDE]

"I would put either a [Littlewoods] instrument, or some sort of thing with a ratchet on that grasps the skin over that side. Using diathermy, I actually ___ actually you do a square, with the instrument holding the skin up, and it turns it into a circle shape." [HCP: BRI0018, Surgeon, Hepatobillary, RDE]

The importance of the skin incision and its variations on PSH rates was not discussed with the majority of the participants. Although BRI0032 felt that the size of the incision may indirectly play a role in increasing PSH rates by increasing the size of the stoma trephine overall.

Interviewer: "Do you think the skin incision is important at all in parastomal hernia prevention?"

Respondent: "The site, or how you make it?"

Interviewer: "Any aspect of it."

Respondent: "Again, whether you use diathermy or a knife, I don't think it makes any difference, whether you, how big you make it, I can't see why that would make a difference, obviously a hernia doesn't involve anything coming through the skin, so I don't see why it should do, other than the fact that probably if you make a bigger skin incision you're likely to make a bigger hole, so only indirectly." [HCP: BRI0032, Surgeon Lower GI, RDE]

c) Effort to achieve shape symmetry

During one of the non-participant observations CM noted that there were efforts made to achieve a symmetry when creating the incision.

> *"The cruciate edges are then joined to make a circle ensuring symmetry." [Observation CM: BRI0034, End Ileostomy, Converted laparoscopic to open, BRI]*

1.8. Subcutaneous adipose

The next layer of the abdominal wall to be surgically altered in order to create the stoma trephine was the subcutaneous adipose tissue (fatty layer beneath the skin). Two variations were identified in how surgeons dealt with this layer, excision or division. Some surgeons felt that there was a difference in PSH rates between those that divided (cut but did not remove fat) and those that excided (removed) the subcutaneous adipose tissue. BRI0009 noted that this was not based on evidence but anecdotally they felt it might make a difference to PSH rates. Participant BRI0022 described how the adipose provided "padding", which may improve PSH prevention.

> *"I used to take out a long column of fat and then I thought, "Well, fat is so compressible, what's the point?" And so I just separate it and cut, you know, in a straight line down to the rectus with some protractors… Well, I'm trying to take away- take away as little as possible, to try and minimise the risk of parastomal hernias. So I don't know if it works or not, but again, it's anecdotal other than evidence-based." [HCP: BRI0009, Surgeon, Upper GI, BRI]*
>
> *Interviewer: "So you think that may have an effect (on PSH rates)."*

Respondent:" Yes…And I think the fatter somebody is the more fat people excise and therefore the bigger the space because the fat retracts around it." [HCP: BRI0015, Surgeon, Lower GI, RDE]

"Some people cut a core out, a cone of fat but I think you lose more tissue. That fat is there for a reason, it is nice padding to hold things in place." HCP: BRI0022, Surgeon, Lower GI, RDE]

"No subcutaneous tissue is excised." [Observation CM; RDE, End Colostomy, Laparoscopic, RDE]

"I try not to excise any of the fat. I leave the fat in place". [HCP: BRI0032, Surgeon Lower GI, RDE]

Other surgeons did not think that variations in adipose excision would make a significant difference to PSH rates. BRI0018 felt this was because the adipose has little strength, and so is unlikely to make a difference to PSH rates:

"I think it doesn't make any difference to parastomal hernia formation because this is anterior to the rectus sheath, so that's not where your hernia comes from. It does make the stoma much neater and nicer for patients, so yes, I excise the adipose tissue and skin, but I don't think it affects the formation of a hernia." [HCP: BRI0010, Surgeon, Lower GI, BRI]

Interviewer: "So you excise the fat, you said, first of all. Do you think that might make a difference to parastomal hernias?"

Respondent: "There's no strength in fat. I think the issue is around the anterior abdominal wall, I suspect." [HCP: BRI0018, Surgeon, Hepatobillary, RDE]

Interviewer: "I notice that you took a cylinder shape of fat."

Respondent: "Yeah."

Interviewer: "They divide it as they do for the rectus. Do you think there's anything in that about, in parastomal hernia prevention?"

Respondent: "I can't see why a bit of fat would make any difference." [HCP: BRI0032, Surgeon Lower GI, RDE]

"I don't think it stops herniation because fat by its nature doesn't really have much tensile strength. I think it probably gives it a cosmetically nicer, fuller stoma." [HCP: BRI0022, Surgeon, Lower GI, RDE]

Where adipose tissue was excised, the participants and the non-participant observations indicated variation in the shape of the adipose removed (either 'cone' or 'column' shaped). The impact of the shape of the adipose tissue excised on PSH rates was not further discussed.

"I would have a cone of fat with a circle of skin on the top." [HCP: BRI0018, Surgeon, Hepatobillary, RDE]

"Surgeon continues to cut out a 'core' of subcutaneous fat that was lying underneath the skin. Littlewoods is moved up and down, side to side, in order to identify where to cut next. The core is approximately the same diameter all the way down." [Observation NB: BRI0033, End Ileostomy, Laparoscopic, RDE]

1.9. Anterior sheath

The incision through the anterior sheath of the abdominal wall was found to vary in size and shape. These factors were thought to be important to PSH development.

a) Shape of the anterior sheath incision

The interviews and non-participant observations indicated the shape of the incision could be either horizontal (transverse), vertical (longitudinal), circular, or cruciate (cross). Furthermore, some surgeons tended to suture the ends of a linear incision ('buttress') to prevent further splitting.

> *"Some people do transverse. Some do longitudinally. Some make cruciate incisions. I've seen people do incisions say either longitudinally or horizontally, and then buttress the ends with suture material, to try and prevent propagation." [HCP: BRI0023, Lower GI, RDE]*

> *"Then you put a suture at the end to try and stop it from tearing." [HCP: BRI0023, Lower GI, RDE]*

The surgeons were divided in their views about the optimal shape of incision. Three surgeons (BRI0023, BRI004 & BRI0015) particularly favoured the circular shape comparted to the linear or cruciate incision, as they felt that the circular would distribute the force better and therefore be less likely to widen. Others like BRI009 favoured the cruciate incision, as this was thought to provide the smallest defect possible. Another favoured the cruciate incision over a horizontal incision as it did not have a 'valve' effect that a linear incision might have.

> *Respondent: "You could do a horizontal. The reason why I wouldn't do a horizontal is I think it might have like a valve effect, so it might actually close the- By virtue of doing it cruciate, in terms of… I think it just doesn't*

compress the bowel as much. I think if you're making a horizontal incision I think you can sort of shut it off."

Interviewer: "And the same would be for vertical?"

Respondent: "And the same would be for vertical, by the way, I think that's what would happen. So, yes." [HCP: BRI0004, Surgeon Lower GI, BRI]"

By contrast, one surgeon (BRI0001) felt the shape would not make a difference to PSH rates:

"No, I don't think it would make any difference whatsoever. I've no idea why I make a cruciate – well, I do: that's what I was taught 20 years ago, so, yes." [HCP: BRI0001, Surgeon, Upper GI, BRI]

While there was some variation in opinion, the majority of clinicians (both surgeons and stoma nurses) appeared to favour the circular incision on the anterior rectus sheath. This is demonstrated in the table below (table 13).

Table 14: Differing opinions on the optimal shape on the incision on the anterior rectus sheath

Favours a circular incision	*"I don't cut across. You'll never see me cut across because I fundamentally believe that circles. You distribute the tension in the abdominal wall greater by having a circle of the smallest diameter that you need to allow the colostomy to come through safely and therefore you get less tangential forces and less tearing." [HCP: BRI0015, Surgeon, Lower GI, RDE]*
	"The other factor I think is maybe the nature of the incision that we make along the sheath. So, by virtue of doing a cruciate incision you are splitting, because you've got a linear incision, it might widen. If we make a circular incision does that mean that the tensal strength or the forces within the abdominal wall, are they going to distribute." [HCP: BRI0004, Surgeon Lower GI, BRI]
	"For those patients who have cruciate incisions, over the years what seems to happen, from my experience, is that those holes get bigger not necessarily in their transverse diameter, or axial diameter when you look at them, but more in the craniocaudal dimension…So when you make a cruciate incision, or you make a longitudinal incision, the point of tension on those is at the ends of the longitudinal incision, and the forces that make the hole get bigger are governed by size of the radius of the abdominal cavity. So these patients will have the greater forces. They've all got things like [Law of Laplace] and ___. Also, ___ get tangential force on the [hole], and [at] the weak point on a cruciate incision, which will change into a diamond ___ and they're the weak points, and the forces will tear out them along the lines of

	weakness, along the cleavage planes… and your surface area of the aperture in that fascia will get bigger over time." *[HCP: BRI0023, Lower GI, RDE]*
	"My thought was it's somewhat akin to a piece of A4 paper. If you want to place a piece of A4 paper into a ring binder, you use a hole punch to create a perfect circle, so that the tension is shared equally around. It's a similar idea. If you make the longitudinal transverse incisions, they have a tendency to propagate over time." [HCP: BRI0023, Lower GI, RDE]
	"I probably ought to go towards actually taking out a ('disc of fascia'?) rather than a cruciate incision, but I just find that easier, so I stuck with that through pig-headedness probably…Only, the only thing I was thinking in theory, and it's a good theory, but you know, the fact that if you've got a circular incision maybe you've got a bit more strength around the radius of it, rather than splitting it." [HCP: BRI0032, Surgeon Lower GI, RDE]
	"I know that some of the surgeons do a cross, and I know that there was a lecture at last year's ASCN regarding doing more of a circular incision." [HCP: BRI0002, Stoma Nurse, BRI]
Favours a cruciate incision	*"The cruciate incision allows the bowel to come through with the minimum defect. So that's why I've avoided doing the circular incision in the rectus sheath." [HCP: BRI0009, Surgeon, Upper GI, BRI]*

The mixed opinions on the optimal incision shape was mirrored in the non-participant observations where a mix of circular and cruciate incisions were observed (although a horizontal incision was not observed).

> *"Fine toothed forceps grasp anterior sheath and diathermy incises a cruciate on anterior sheath" [Observation CM: BRI0033, End Ileostomy, Laparoscopic, RDE]*

> *"The surgeon places a Littlewoods on the sheath, and lifts it up. Forceps diathermy is used to make an incision in the sheath. The surgeon makes a circular shape around the Littlewoods." [Observation NB: BR0021, End Colostomy, Laparoscopic, RDE]*

b) Size of the anterior sheath incision

Most surgeons felt that the size of the anterior sheath trephine was important for PSH prevention.

> *"If technically it's been made with a very large hole, then I think that would definitely lead to a parastomal hernia…I think the size of the cruciate incision, both on the anterior and the posterior layers of the rectus sheath, matter. I think that that's probably, I think, what matters most." [HCP: BRI0001, Surgeon, Upper GI, BRI]*

> *"Other factors (relating to PSH prevention) would be to do with the size of the cruciate incision, as well." [HCP: BRI0004, Surgeon Lower GI, BRI]"*

The perceived 'ideal' size appeared to vary depending on the surgeon's preference, the patient's size, whether the procedure was an emergency or not, and the part of bowel being brought out (small or large bowel).

> *"Aiming for something that's no bigger than about 2.5cm, 3cm maximal diameter." [HCP: BRI0004, Surgeon Lower GI, BRI]*

> *"It's only going to be 2cm or 3cm" [HCP: BRI0001, Surgeon, Upper GI, BRI]*

> *"Some people would say two fingers, but my two fingers are bigger than your two fingers, so I think you have to see the patient in front of you and you need to see their bowel. I try to do it about 1.5cm – for an ileostomy – about 1.5cm from the ileus, and for colostomy, 2cm about." [HCP: BRI0010, Surgeon, Lower GI, BRI]*

> *"The problem with two finger breadths to go through is my two finger breadth, for me, you're looking at about 3.5cm, perhaps more. Actually, that's quite a size trephine to go through, and possibly almost too big. It's 2cm or two finger breadths. The traditional has been one finger in, one finger in, and a bit of pulling and tearing and everything else." [HCP: BRI0023, Lower GI, RDE]*

> *"Other factors (relating to PSH prevention) would be to do with the size of the cruciate incision, as well. To be honest, we don't always… You kind of make that incision relative to the size of the patient, sometimes. It also depends on the urgency with which you're doing the case." [HCP: BRI0004, Surgeon Lower GI, BRI]"*

1.10. Formation of the muscle trephine

Two key variations when creating the muscle trephine (the hole in the muscular layer of the anterior abdominal wall) were identified. These were whether the muscle was split or divided. All surgeons reported that they would split (separate) the muscle layer rather than divide (cut) it. Splitting the muscle was overall felt to be superior to cutting for PSH preventions. The latter was suspected to lead to heavy bleeding, de-vascularisation and/or de-innervation of the muscle which can predispose to wound infections and subsequently lead to the development of a PSH:

"Respondent: If you de-vascularise any muscle fibres and it becomes infected then infection leads to hernia formation there is no doubt about that.

Interviewer: So, splitting of the fibres improves that rather than incising them?

Respondent: I think it does, I can't show you evidence to say that. Logically to me if you are splitting the fibres and not disrupting my cutting through the fibres and all the blood supply to the muscle and the surrounding area." [HCP: BRI0022, Surgeon, Lower GI, RDE]

"I think if you cut it, particularly if you go through with diathermy, you risk de-innervating it, so there will be an atrophy. Also, there's a risk particularly that you may damage the inferior epigastric vessels, and you will end up over time [with ischemic 1:22:29] atrophy." [HCP: BRI0023, Lower GI, RDE]

Interviewer: "Do you think that, if you were to divide the muscle as well, it would make a difference?"

Respondent: "Yes, I think it would make it worse."

Interviewer: "Make it worse, so if you made an incision in the muscle rather than-?"

Respondent: "Yes, because the muscle is sort of reinforcing it because it [presumably] comes back in, but I've never read anything about that." [HCP: BRI0001, Surgeon, Upper GI, BRI]

"I tend to (split the muscle) do that with instruments, with straight-bladed scissors, mayo scissors. With the rectus muscle it's quite clear where the line of the fibres is running, so I just choose where to go and just split longitudinally in the line of the fibres, then use retractors, which are called retractors, and then split apart the muscle so that I can then see the posterior sheath. But I don't ever try and divide the rectus muscle to get a bigger space, I always split it… I think if you start making incisions I think you're more at risk at damaging muscles- Not muscles, the nerves that run into the abdominal wall." [HCP: BRI0004, Surgeon Lower GI, BRI]

"I would try and avoid dividing I don't think there is a need to divide the muscle you know it retracts quite nicely. It also bleeds like stink." [HCP: BRI0036, Surgeon, Lower GI, BRI]

1.11. Posterior sheath

Some surgeons felt that the incision made on to the posterior sheath when creating the stoma trephine was important to PSH prevention, while others did not.

"I've always thought the anterior sheath would be most important but there's no reason behind that, the anterior and posterior sheath they're the

important ones, peritoneum skin is not so important." [HCP: BRI0036, Surgeon, Lower GI, BRI]

"Posterior sheath is very weak, certainly below the arcuate line. Now above that I don't know, there's a bit more fascia there, the posterior sheath, but it probably doesn't make that much difference." [HCP: BRI0032, Surgeon Lower GI, RDE]

a) Shape and size of the posterior sheath incision

Variation were found in the way the surgeons may create the incision on the posterior sheath. This includes the size and the shape of the incision. The significance of these variations was not discussed in the same amount of detail as the size and shape of the anterior incision. BRI0001 felt that the size of the incision made on the posterior sheath was "what matters most" but did not elaborate further. BRI0023 felt that the posterior sheath had little strength anyway so variations of the incision would not contribute significantly to PSH prevention. Many surgeons still commented on how they would approach the incision on the posterior sheath in detail and as demonstrated by the quote from BRI0022 still have a careful attitude toward it.

"In terms of technique, I think the size of the cruciate incision, both on the anterior and the posterior layers of the rectus sheath, matter. I think that that's probably, I think, what matters most." [HCP: BRI0001, Surgeon, Upper GI, BRI]

"In my view the incision in the posterior sheath is of less importance. The reason being, if you're below the arcuate line, [as we will be discussing as part of that 1:23:14], you may just be on to the peritoneum, and the hole that you make in the peritoneum is of little or no consequence. If you are at the arcuate line of Douglas, the strength of the posterior sheath

___[1:23:35] is not great anyway. So its contribution to the prevention of parastomal hernia is relatively minimal, in my view." [HCP: BRI0023, Lower GI, RDE]

"I think with the posterior sheath because it can be quite flimsy in nature you get into that plane. I don't want to cut it too much to disrupt it. Sometimes it is a case of pulling the bowel through the hole and feeling if it feels tight or not. What you don't want to do is cut the posterior sheath too much and then it is really saggy. It is better to pull it through and think, "That is a bit snug." Then making a bit of a nick in the posterior sheath to make it a bit wider or using your Langenbeck's to sometimes just stretch it. That does vary between whether you do that sharp or blunt." [HCP: BRI0022, Surgeon, Lower GI, RDE]

"I also make a cruciate incision, correspondingly, on the peritoneal surface as well, and on the posterior sheath, split the rectus muscles in the line of their fibres. This is very crude, but I use something called the 'two finger test' because my hand isn't particularly large, in gloves I know that two of my fingers - my middle finger and my index finger - if they will pass through fairly well through that defect I can get the colon through without there being too much in the way of constriction." [HCP: BRI0004, Surgeon Lower GI, BRI]"

"Two tissue clips grasp posterior sheath. Curved scissors incise 2cm vertical hole in posterior sheath." [Observation CM: BRI0033, End Ileostomy, Laparoscopic, RDE]

"SpR then makes a further incision on the posterior sheath cruciate 2cm." [Observation CM: BRI0037, End Colostomy, Open, BRI]

"I then make a transverse incision in the posterior rectus sheath" [HCP: BRI0023, Lower GI, RDE]

b) Other variations for the posterior sheath incision

It was observed that a surgeon may also use a trocar (a laparoscopic instrument that acts as an introducer) to pierce the posterior rectus sheath. Surgeons interviewed also reported that they could use blunt force to penetrate the posterior sheath. Though they did not mention whether or not they thought this may have an impact of PSH rates.

"The SpR then uses the 5mm port to pierce the posterior sheath, the port remains and the introducer is removed." [Observation CM: BRI0014, End Colostomy, Laparoscopic, RDE]

Interviewer: "In real life they just kind of push through it and separate it. Would you say that's common?"

Respondent: "Yeah. I'd say that was very common. I have seen people, I've done it myself." [HCP: BRI0032, Surgeon Lower GI, RDE]

1.12. Enlarging the trephine

During the non-participant observations, it was noted that sometimes efforts were made to widen/enlarge the trephine following its initial creation. This could be done by either blunt force or incision. Incision technique could vary (either by diathermy, scalpel, or by using scissors).

"With the surgeon's index finger he checks for snugness of the trephine. On deciding it is too tight he requests a langenbeck retractor and places it along side his finger, asking the SpR to hold it and retract. Using mackindo scissors he makes a further incision in the peritoneum. Consultant re-checks for snugness on either side of the stoma, checking from inside of the abdomen and outside" [Observation CM: BRI0034, End Ileostomy, Converted laparoscopic to open, BRI]

"Further fibres of muscles/fascial tissue are cut with diathermy" [Observation NB: BRI0021, End Colostomy, Laparoscopic, RDE]

"Then we place some dissecting scissors along the side of the trocar to open them up a bit." [HCP: BRI0022, Surgeon, Lower GI, RDE]

"It is better to pull it through and think, "That is a bit snug." Then making a bit of a nick in the posterior sheath to make it a bit wider or using your Langenbeck's to sometimes just stretch it. That does vary between whether you do that sharp or blunt." [HCP: BRI0022, Surgeon, Lower GI, RDE]

Unfortunately, it is not discussed whether or not the participants felt that these variations of stoma formation relate to PSH formation though one surgeon (BRI0023) felt that there may be a difference between diathermy and scalpel/scissors due to the greater damage to cause using diathermy and so these variations in technique may still be appropriate for further exploration during the CIPHER study.

Interviewer: "Do you think use of diathermy versus other methods of incising the anterior sheath would make a difference?"

Respondent: "I don't know. Not certain. People have hypothesised over time that the method that you use to go through the fat may alter things like seroma formation, but whether or not it alters hernia rate formation is not something that I've necessarily thought of…Because of the damage that you get from the use of diathermy it's often hypothesised that you end up with greater rates of inflammatory cytokines around, which then leads to an exudate forming injury and you get greater rates of seroma formation."

Interviewer: "So it could in theory make a difference? Do you think it alters healing using diathermy?"

Respondent: "Possibly, yes... the plastic surgeons almost always perform the abdominoplasty portion using a knife and/or scissors. Using clips and ties to ligate the perforating vessels from the inferior and superior epigastric vessels. Rather than using diathermy. They try to keep that to a minimum." [HCP: BRI0023, Lower GI, RDE]

One surgeon noted that there may be a risk of tearing the muscle when enlarging the trephine:

"What you try not to do is to tear open the sheath by excessive force on it." [HCP: BRI0023, Lower GI, RDE]

1.13. How trephine measurements were made

Differing techniques for measuring the adequacy of the size of the stoma trephine were reported amongst the surgeons. Some used 'by eye', some used 'finger breaths' and some reported a combination approach. No one reported using a tape measure or was observed to have used one.

Interviewer: "How do you measure it"?

Respondent: "Eyeball." [HCP: BRI0023, Lower GI, RDE]

"Then you need to actually think about the size of that gap, and more by teaching and training one tends to see if one can fit four fingers through it." HCP: BRI0018, Surgeon, Hepatobillary, RDE]

Interviewer: "How did you measure that? By eye?"

Respondent: "Finger and size of bowel" [Observation CM: BRI0037, End Colostomy, Open, BRI]

Respondent: "I don't measure it, I measure it by eye."

Interviewer: "Do you ever do the finger breadth thing?"

Respondent: "I don't actually, no." [HCP: BRI0022, Surgeon, Lower GI, RDE]

The imprecision of finger breaths concerned one surgeon (BRI0023) as there is a lot of variation between one surgeons finger breaths and another's. BRI0010 also felt that using finger breaths was "subjective".

Interviewer: "What do you think of people who use the breadth of their fingers?"

Respondent: "Traditional textbook teaching talks about two finger breadths to go through. The problem with two finger breadths to go through is my two-finger breadth, for me, you're looking at about 3.5cm, perhaps more. Actually, that's quite a size trephine to go through, and possibly almost too big. It's 2cm or two finger breadths. The traditional has been one finger in, one finger in, and a bit of pulling and tearing and everything else." [HCP: BRI0023, Lower GI, RDE]

"Well, it's very subjective. Some people would say two fingers, but my two fingers are bigger than your two fingers." [HCP: BRI0010, Surgeon, Lower GI, BRI]

During the non-participant observations, it was observed that one of the surgeons assessed for 'snugness'. They did this by using their fingers to assess the space between the bowel and the stoma trephine. The significance of snugness was also mentioned in an interview with BRI0022 but they did not remark on whether or not the felt this was significant for PSH prevention.

"With the surgeons index finger he checks for snugness of the trephine. On deciding it is too tight he requests a langenbeck retractor and places it along side his finger, asking the SpR to hold it and retract. Using mackindo scissors he makes a further incision in the peritoneum. Consultant re-checks for snugness on either side of the stoma, checking from inside of the abdomen and outside." [Observation CM: BRI0034, End Ileostomy, Converted laparoscopic to open, BRI]

"It is better to pull it through and think, "That is a bit snug." Then making a bit of a nick in the posterior sheath to make it a bit wider or using your Langenbeck's to sometimes just stretch it. That does vary between whether you do that sharp or blunt." [HCP: BRI0022, Surgeon, Lower GI, RDE]

1.14. Variations specific to laparoscopic procedures

Some stoma formation variations were specific to laparoscopic procedures, as discussed below.

a) Deflating the abdomen before creating the stoma trephine

BRI0036 felt strongly that a surgeon aiming to prevent a PSH should deflate the abdomen to prevent stretching of the trephine (which could lead to subsequent PSH).

Respondent: "I would generally deflate, I think it's important to deflate the abdomen before making a stoma cut…so from what we've talked about so far, what you want is a hole that's closely mirrors the diameter of the bowel so not too much so that you can get a parastomal hernia, not too little so that it… you're gonna get it pinched. so to create that doing it under tension with um the CO2 inside pushing up against the fascia just doesn't make sense to me."

Interviewer: "So you're gonna get a bigger hole?"

Respondent: "Potentially you know just… if you want to get the right size hole doing it under tension when there's something underneath pushing it up uh which you don't have direct control over doesn't seem like a good idea to me I would do it without tension." [HCP: BRI0036, Surgeon, Lower GI, BRI]

A different surgeon was observed to have asked for "gas off" before bringing the end of the bowel out of the stoma trephine (non-participant observation BRI0014), possibility due to the theory set out above.

b) Stoma trephine used as an extraction site

Other technical factors relevant to laparoscopic stoma formation that were perceived to increase the risk of PSH included the use of the stoma trephine as an extraction site (i.e. where the stoma trephine was used to remove the excised piece of bowel). This was usually the diseased section of bowel, which could be enlarged due to inflammation, and thus suspected to stretch the stoma trephine when it was removed from the abdomen through the stoma trephine:

"Um so I did a little study when I was a registrar on this and we looked at um who developed parastomal hernias in laparoscopic versus open

procedures and what we found and what I feel strongly about is when you use the stoma site to extract a specimen you do predispose them to parastomal hernias so if you're doing a, predictly if you're doing a subtotal colectomy which is the way it's tempting to do it, you're taking a diseased colon out through a hole which eventually is gonna become an ileostomy site and yes you can narrow it down with sutures afterwards but if we know that parastomal hernia repairs, repair by these sutures have an almost 100% recurrence rate then it's gonna get a parastomal hernia. So whenever I do a laparoscopic subtotal colectomy I will try and do a separate extraction site to uh get a form of the, the stoma and yes that gives them a bigger wound, bigger than the others but I think it is important… you're making a hole to get the colon out which is um you know much bigger than the small bowel you're gonna leave there eventually. So technically if you do make the hole too big you're get a parastomal hernia there's no doubt about it." [HCP: BRI0036, Surgeon, Lower GI, BRI]

"You then have to create a very large hole for the specimen to come out of, and, as we discussed before, the size of the hole… Once you've made it big, making it smaller again is really challenging." [HCP: BRI0023, Lower GI, RDE]

This practice was also observed in the non-participant observations.

"The specimen is handed out. With the specimen removed, I can now see that all that bowel did seem to come out of the stoma hole. Impressive! Won't that have stretched it?" [Observation NB: BRI0033, End Ileostomy, Laparoscopic, RDE]

c) Conversion of the stoma trephine into a port site

Another technique observed in laparoscopic stoma formation was the conversion of the stoma trephine site into a port site, by creating an air seal around the trephine using a surgical glove and an Alexis wound retractor. This technique was observed during the non-participant observations:

> *"With the other hand, the surgeon takes a clip and picks something up. It looks thin so I'm guessing it's peritonem and the previous incision (and spreading) was through the layers of the abdominal wall. The surgeon then places a similar clip adjacent to the first, pinches the tissue between fingers, then cuts the tissue between the two clips. The Langenbecks are then placed inside the new plane – i.e. within the abdomen. The surgeon then places an Alexis retractor into the hole. A glove is placed over the top. The surgeon and assistant roll the edges of the Alexis so that it is close to the patient's skin. The surgeon cuts a small amount of plastic off the top of the middle finger of the glove. A 10 (or 12) port is then placed through the hole and a suture tightened and tied around the glove. The gas tubing is then connected to the port. The patient's abdomen begins to increase in size. The operating lights are then turned off. The surgeons puts the camera inside and swings it around the abdomen." [Observation NB: BRI0033, End Ileostomy, Laparoscopic, RDE]*

While surgeons in the RDE favoured this technique, another surgeon from Bristol felt that this technique would subsequently widen the trephine and lead to an increase risk of PSH development:

> *Interviewer: "I've seen people perform laparoscopic surgery through the stoma site…so will use a wound protector and a glove do you think that will have an affect on parastomal hernia rates?"*
>
> *Respondent: "Yea I think exactly the same reason so I don't do it. Nice idea I know people are desperate to keep their wounds down but if you've got a sub total colectomy for a permanent ileostomy which is with the patient for the rest of their life I think you're gonna get a hernia and they would probably, I have never actually done it with anyone but they would probably narrow the stoma hole down later and they're using stitches and*

yet we've said that, that repairing a parastomal hernia with stitches has got a 100% recurrence rate" [HCP: BRI0036, Surgeon, Lower GI, BRI]

Alternatively, a site initially intended as a port site may also be converted into the stoma trephine site.

> *"It is a similar approach in that you take the disc of skin, dissect down until you get to the peritoneum and you split the muscle fibres. Everything is the same other than you just pass a trocar through the peritoneum which you then stretch when you are pulling the colon up." [HCP: BRI0022, Surgeon, Lower GI, RDE]*

1.15. Other technical factors

a) Use of a wound protector

The use of a wound protector to facilitate stoma formation or delivery of the excised bowel through the stoma trephine was commented on by BRI0023. While the surgeon felt that this may improve surgical outcomes they suspected this would worsen PSH rates, although the mechanism through which this would occur was not discussed.

> *Respondent: "For patients who have had obstructive bowel difficulties, in getting the bowel through the abdominal wall, particularly in those patients who are quite morbidly obese, I will sometimes use an Alexis wound retractor, to try and facilitate the delivery of the stoma through the abdominal wall. So the polyurethane lining to it can be easily lubricated with either some of the patient's own bodily fluids from the abdominal cavity, or jelly, to allow the easy passage of the stoma through the abdominal wall. So that you don't tear the mesentery, which is often thickened and inflamed but which contains the important blood supply to the stoma. Because if that gets damaged then the patient ends up with stenosis and retraction.*

Interviewer: "Do you think that will improve herniation rates just because there's less trauma?"

Respondent: "It probably worsens herniation rates, but in those patients what you're interested in is getting the patient off the table alive. Usually they're emergency surgery, peritonitis, perforated, diverticular disease. You're never going to end up with a stoma reversal because of their age and comorbidity." [HCP: BRI0023, Lower GI, RDE]

b) Squeezing the bowel to reduce oedema during bowel delivery

During a non-participant observation, a surgeon was observed squeezing the section bowel that was used to create the stoma before it was sutured to the skin..

"The surgeon can be seen placing a swab over the bowel and ?squeezing the end of the bowel." [Observation NB: BRI0014, End Colostomy, Laparoscopic, RDE]

c) Widening of the stoma trephine

As discussed previously, the stoma trephine may require widened following an assessment of snugness. This can be performed using incision or force. Sutures were also reported to sometimes be required following this if too much widen occurs. The impact that these variations may have on PSH rates was not discussed with the clinicians during interview.

"On deciding it is too tight he requests a langenbeck retractor and places it along-side his finger, asking the SpR to hold it and retract. Using mackindo scissors he makes a further incision in the peritoneum." [Observation CM: BRI0034, End Ileostomy, Converted laparoscopic to open, BRI]

"The traditional has been one finger in, one finger in, and a bit of pulling and tearing and everything else." [HCP: BRI0023, Lower GI, RDE]

"The other thing is whenever I, if I ever widen the trephine to deliver a specimen, I then to tend to put a couple of stitches in to try and narrow it again, but I don't think that's as good as not opening it in the first place, if that makes sense.

Interviewer: Do you think they'd help though? A little?

Respondent: Probably better than completely leaving it open." [HCP: BRI0032, Surgeon Lower GI, RDE]

d) Fascial fixation

Fascial fixation is the act of attaching the stoma, either the bowel wall (serosa) or the mesentery (the bowels attachment to the posterior abdominal wall where its blood supply derives from) to the anterior abdominal wall (122). Fascial fixation was discussed in some of the interviews, and appeared to be performed by some surgeons, but not others. This practice was not observed in any of the operations. Some surgeons theorised (BRI0023) that this technique could influence PSH formation by closing a space where a hernia could form, while others were unsure (BRI0009):

Respondent: "And the other issue is whether you actually tack the serosa to the fascia or not, which I don't do, mainly because most of the stomas I make are reversible, and I think anything that I can do to make it easier to reverse is probably going to help."

Interviewer: "Do you think that may benefit parastomal hernias prevention though tacking?"

Respondent: "I think having a permanent one, potentially closing the space, you know, probably in the short term, you know, before a bit of bowel has a chance to sort of get its foot through the door metaphorically, after you're closing that space off so there's nothing that can sneak around *there while you're waiting for a bit of fibrosis to form, makes sense to me." [HCP: BRI0032, Surgeon Lower GI, RDE]*

Respondent: "The other thing maybe is whether or not you choose to [tack] the stoma, or choose to tack the bowel to the fascia. So, in does that somehow reduce your risk of parastomal hernia formation? Again, I don't know."

Interviewer: "You mentioned tacking the outer fascia, how would you do that?"

Respondent: "I would do that with sutures, if I would do it, I don't normally do that. But you've got to remember, a lot of patients that we operate on are obese, in the modern age, or overweight, and the practicality of actually physically being able to do that is… "

Interviewer: "And would you tack, well, suture the mesentery or would you suture the bowel".

Respondent: "I would suture the serosal surface. That's another thing; I don't do any tacking of the mesentery to anything, it's just literally bowel wall." [HCP: BRI0004, Surgeon Lower GI, BRI]"

Respondent: "I don't tend to suture it to the rectus sheath as well, in the case of an ileostomy, but for colostomies, because they're flat, I tend to suture it to the rectus once it's at the right level. And then slightly evert it as well onto the skin. Bowel to the rectus, just to try and minimise retraction of the stoma…

Yes, well it's- I do it- most of the time when I'm performing a stoma, it will be in the emergency setting and so they tend to be patients who are oedematous or have an ileus and I don't like the stomas retracting too much".

Interviewer: "And so how many- do you do one stitch into the rectus or do you do..?"

Respondent: "Sort of four quadrants."

Interviewer: "And do you think that will make a difference to parastomal hernias?"

Respondent: "I don't know. I don't think that's- like you said, it's not something that's published…The colon, I suture the colon to the rectus and to the skin separately." [HCP: BRI0009, Surgeon, Upper GI, BRI]

e) Mesentery stripping

Mesentery stripping, the removal of part of the stoma mesentery, was both discussed in interviews and observed. One surgeon BRI0036 felt that this could contribute to PSH development as removing the bowel's mesentery could affect the stoma's blood supply:

"What you're trying to avoid is stripping the mesentery off, cos if you strip the mesentery off the bowel it's ischemic and it will go dusky and flat so you might create a bigger whole and then you've got a risk factor for parastomal hernia." [HCP: BRI0036, Surgeon, Lower GI, BRI]

One of the surgeons also reported removing 'appendices epiploica', fatty tissue that protrudes off of the colon that is not the mesentery and doesn't contain a blood supply:

"If the appendices epiploicae are large I'll remove them but I want it under no tension and subcuticular to extramucosal sutures with all the knots buried." [HCP: BRI0015, Surgeon, Lower GI, RDE]

f) Closure of other wounds

Closure of other abdominal wounds (e.g. midline laparotomy incision and or port sites) was theorised to be important to PSH prevention. Participant BRI0023 highlighted the importance of restoring the anterior abdominal wall's function through good closure of the deep layer of the abdominal wall, using small-bite closure instead of large bite closure:

"Other things to think about. How you close the abdominal wall I think is really important, because it then affects how likely the patient is to develop an incisional hernia. If the patient develops an incisional hernia that will impact, because of the mechanics of the abdominal wall on the stoma aperture and then lead to development of parastomal hernias. The two are intimately related. You have to take every possible step to ensure that you have good abdominal wall closure, and restoration of appropriate function, so we tend to use the small bite closure technique using 2-0 PDS delayed absorbable sutures. It's been standard practice now for about two years, particularly for primary surgery." [HCP: BRI0023, Lower GI, RDE]

Participant BRI0018 reported that they would close the other wound sites before suturing the abdominal stoma. This was the practice observed during the non-participant observations.

"At this point the end of the bowel that I've brought through is typically stapled off, and I will leave it stapled off when it's drawn through the stoma. Then we would finish any further intra-abdominal work, close the anterior abdominal wall, close the skin, dress the skin." [HCP: BRI0018, Surgeon, Hepatobillary, RDE]

"Right (patient left) sided port site closed with deep tissue suture (PDS). Ileum now covered with swab. Anterior medial port site and lower suprapubic ports sites already closed during video break. Superficial aspect of wounds closed with glue only, no cutaneous sutures, by SpR while the consultant manually closes the wounds with his hands. Ileum manipulated by SpR to descend into trephine further, using both index fingers." [Observation CM: BRI0033, End Ileostomy, Laparoscopic, RDE]

"4.0 monocryl on curve and JPS sutures close midline umbilical port site. Mostly out of view with the handheld. Monocryl for port smaller lateral port sites. Wet and dry. Glue used (theory to reduce stoma infections). Two babcocks on distal edges of stapled stoma. Out of view. Lotus dissects the stapled line. Fine tooth forceps and 4.0 monocryl on curve secures stoma to skin with slight spout at 3, 12, 9 then 6 o'clock positions." [Observation CM:BR0021, End Colostomy, Laparoscopic, RDE]

During the non-participant observations, the abdomen was observed to be cleaned before suturing of the stoma was performed. Use of glue as a dressing was also discussed as a variation in stoma formation and was also observed in the non-participant observations. The perceived implications of this for PSH development were not discussed.

"The skin is then cleaned with sterile water and dried. Glue is applied on top of the subcuticular sutures." [Observation CM: BRI0014, End Colostomy, Laparoscopic, RDE]

"Typically I would use a glue to give you a seal. Then you haven't got a dressing extending from the edges of the main wound, that might impinge on where your stoma bag would sit. Also the glue, even if there are

leakages, will give you a seal over the centre of the wound." [HCP: BRI0018, Surgeon, Hepatobillary, RDE]

"There is glue over the skin on the laparotomy wound." [Observation CM:BR0030, End Colostomy, Open, BRI]

"Glue is applied on top of the subcuticular sutures." [Observation NB: BRI0014, End Colostomy, Laparoscopic, RDE]

g) Securing the stoma site

Variations on how the stoma was secured to the stoma trephine were both discussed and observed during the mixed qualitative methods research. The stoma may be spouted (protrudes above the skin) or un-spouted (lies flush to the skin). See Figure 14: Spouted and un-spouted abdominal stoma. BRI0010 felt this may be important for prevention stoma retraction but did not mention whether or not this would be an important variation that may affect PSH rates.

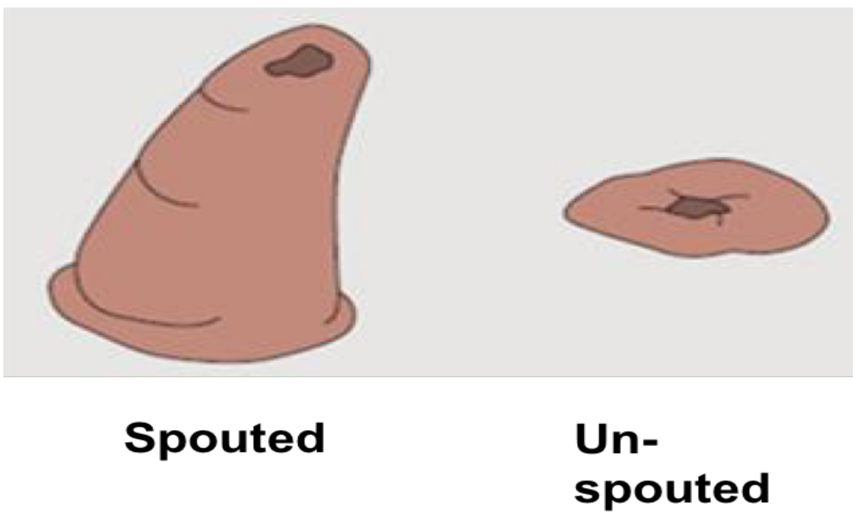

Figure 14: Spouted and un-spouted abdominal stoma

"If I think there is going to be a problem with stoma contraction with an end colostomy then I sometimes make a small spout on the stoma, so you basically stitch back onto the serosal surface just to allow it to spout slightly. But if I don't think there is going to be an issue with retraction of the stoma then I will do it flush with the skin surface." [HCP: BRI0004, Surgeon Lower GI, BRI]

"They favour making a spouted colostomy rather the classic flush one. Taking a bite of the dermis lower down in the colon and then through the colon mucosa to try and spout the stoma." [HCP: BRI0022, Surgeon, Lower GI, RDE]

"Traditional teaching is that a colostomy should be flush, but I don't make it flush to the skin, I try to spout it a tiny bit, about half a centimetre of spout, because by the time it settles, then it becomes flush. If you start it as flush, it's going to sink in and retract back." [HCP: BRI0010, Surgeon, Lower GI, BRI]

A surgeon may also secure the abdominal stoma to the stoma trephine using different techniques. Though it is not clear if these variations are likely to make a difference to PSH rates.

"Subcuticular bite, followed by a superficial bite (further down) then full thickness bite in the bowel wall right by the cut edge. Clipped. 6 o'clock position. Similar stitches at 9 o'clock, 12 and 3. A bit of fat attached close to the edge of the bowel wall is dissected away using the harmonic. The sutures in all four quadrants are then tied and cut…The surgeons fill in the gaps between the sutures with 1x bowel and 1x subcuticular bites. NB they are subcuticular rather than going through the skin. The skin around

the stoma is cleaned and a bag applied." [Observation NB: BRI0021, End Colostomy, Laparoscopic, RDE]

"The surgeon takes a subcuticular bite, then a superficial bite of bowel wall (quite some distance away from the opening), then at the opening of the bowel." [Observation NB: BRI0033, End Ileostomy, Laparoscopic, RDE]

"Further sutures are placed in between the gaps and tied. No fat is left exposed." [Observation NB: BRI0014, End Colostomy, Laparoscopic, RDE]

"Starting at the 3 o'clock position a full thickness skin bite is taken and then two stoma serosal bites, very close together, one on the cut stoma edge and one just below and tied." [Observation CM: BRI0037, End Colostomy, Open, BRI]

"Stapled edge of stoma has been removed and cut edge of stoma is being secured to the skin without spouting. Interrupted full thickness sutures through the stoma edge and skin until there are no spaces between the mucocutaneous junction." [Observation CM:BR0030, End Colostomy, Open, BRI]

h) Use of local anaesthetic at the stoma site

During one non-participant observation, a surgeon was observed applying local anaesthetic around the finished stoma site. This variation was not discussed further so it is unclear if this may have an impact of PSH development.

"Finally, they put local anaesthetic into the subcutaneous tissue, and measure the diameter required for the stoma bag." [Observation NB: BRI0033, End Ileostomy, Laparoscopic, RDE]

2. Non-technical factors

The remaining non-technical factors identified during the mixed qualitative methods research are discussed below.

2.1. Non-technical surgical factors

Non-technical surgical factors also arose from the interviews, defined as factors relating to the surgery that cannot be attributed to a variation in surgical technique. These included the grade, speciality and competency of the surgeon, the context of stoma formation (e.g. time of day and urgency of the procedure) and the pre-operative consultation of a stoma therapist. Surgeons and stoma nurses alike cited these to be important for PSH prevention.

a. Emergency surgery as a risk factor for PSH

Almost all of the surgeons considered the context of stoma formation to be very important to PSH prevention. All reported that PSH formation was more common when the surgery was performed as an emergency rather than as an elective planned procedure. This was theorised as being due to increased wound infection risk, a more oedematous bowel, the greater likelihood that the surgeon would not be a colo-rectal surgeon (suggesting inexperience) or being forced to place the trephine in a location that they would not consider to be ideal (due to stoma nurses being less accessible out of hours).

"Because if the bowel is very oedematous and obstructed, which it often is for emergency surgery, then you may need to have a bigger trephine. You make a judgement… and often in the emergency setting you're kind of forced anyway where to put it, because you're just depending on where you can or where they've had previous surgery…Obviously, if technically

it's been made with a very large hole, then I think that would definitely lead to a parastomal hernia, but the majority are quite snug because in the emergency situation, if the bowel is swollen, then it is snug. Obviously the bowel, when it shrinks back down, there's the potential for it being loose, but I think it's because there is automatically a kind of defect and a weakness there." [HCP: BRI0001, Surgeon, Upper GI, BRI]

"I tell you what would make think that they were going to have a parastomal hernia, is if the stoma was formed in an emergency setting." [HCP: BRI0004, Surgeon Lower GI, BRI]

"I would have thought emergencies are more likely to develop them, especially septic cases where there's been contamination within the abdominal cavity already. And I would have thought operating on obstructed bowel and bringing out stomas through larger defects would be more associated with a parastomal hernia." [HCP: BRI0009, Surgeon, Upper GI, BRI]

"Well, the emergency setting, the key difference is they're not pre-marked. They don't have a chance to meet the stoma nurses. Rarely they would see them if they are being done during the day, but if they're done in the middle of the night they don't. It's just your assessment of where you're going to put the stoma and it could be in completely the wrong place." [HCP: BRI0010, Surgeon, Lower GI, BRI]

"I think it does affect parastomal hernia rates as well. Emergency surgery always does because they're likely to be done – it's not always by the

colorectal surgeons, not always by a registrar who is a colorectal trainee and even those done by colorectal surgeons have problems, so I can imagine those who are not used to doing them would have more problems…It's just because there is an emergency situation and people are not using to doing stomas on a daily basis or on a weekly basis, you might bring it wherever you think is easier at 2 o clock at night.…I think if you're operating on somebody with a large bowel obstruction and they have a hugely dilated bowel, what you end up doing is you end up making a bigger hole to bring that piece of bowel out. As a result, when the bowel goes back to normal size after the obstruction, you've created a parastomal hernia… So emergency surgery, I think obstruction probably and peritonitis are probably the two factors that result in parastomal hernia." [HCP: BRI0010, Surgeon, Lower GI, BRI]

"A patient coming in as an emergency who is dehydrated is likely to have more comorbidities. They might have intra-abdominal sepsis, potentially cardiovascular compromise and hypertension, anything that is going to affect the blood supply to the patient. If they have got a systemic inflammatory response going on they are much more likely to have parastomal herniation. You are going to be dealing with oedematous bowel probably because you are probably dealing with some sort of obstruction or sepsis intra-abdominally. Emergency definitely will increase your risk parastomal herniation." [HCP: BRI0022, Surgeon, Lower GI, RDE]

b. Timing of surgery

One surgeon felt the time of day the surgery was performed at may make a difference but that this was likely to be a surrogate for emergency surgery which is often performed at night.

"Out of hours is not going to be as good as in-hours, emergency not as good as elective." [HCP: BRI0032, Surgeon Lower GI, RDE]

"Interviewer: Do you think time of day would affect anything?

Respondent: Well I think time of day, it's a surrogate marker for urgency of procedure, so if you're doing something in the night, by definition that's an urgent procedure. So, yes, I would say it probably would" HCP: BRI0004, Surgeon Lower GI, BRI]

"It is also ideally the patient being marked beforehand which as an emergency we can't always do because we don't have the stoma nurses." [HCP: BRI0022, Surgeon, Lower GI, RDE]

c. Surgeon specific factors

The participants felt that surgeon specific factors were important for PSH prevention. There was an assumption that senior surgeons and colo-rectal specialists had more skill in forming stomas that were resistant to PSH prevention.

"(A technical error) done by people who are junior, don't know what they're doing, particularly in emergency surgery." [HCP: BRI0023, Lower GI, RDE]

"Yes, probably. I would like to think that a colorectal specialist would be better at this than I am and better than a trainee. Maybe they use things that make a difference, but I'm not sure about that." [HCP: BRI0001, Surgeon, Upper GI, BRI]

"I'm sure that colorectal surgeons who make stomas electively more regularly than other specialties are going to have a better stoma technique than non-colorectal surgeons." [HCP: BRI0009, Surgeon, Upper GI, BRI]

"I think it does affect parastomal hernia rates as well. Emergency surgery always does because they're likely to be done – it's not always by the colorectal surgeons, not always by a registrar who is a colorectal trainee and even those done by colorectal surgeons have problems, so I can imagine those who are not used to doing them would have more problems." [HCP: BRI0010, Surgeon, Lower GI, BRI]

"I think overall a subspecialised consultant colorectal surgeon who does lots of stomas, reads the literature and does things for a reason is likely to have less complications than an upper GI surgeon who performs the odd stoma on-call very rarely. I think it is important, but again that doesn't always hold true because old-school general surgeons could do everything and probably do everything quite nicely." [HCP: BRI0022, Surgeon, Lower GI, RDE]

d. Level of supervision if consultant not performing the stoma formation

One senior surgeon felt that the level of supervision when a junior surgeon is forming the stoma was also important for PSH prevention.

"The other things about stoma formation I think tend to be important is in terms of who does it. Even if the trainee is doing it I will still be scrubbed in at the table. I don't leave them until it's done…Even with very, very senior [peri] fellowship registrars I will be there. I will be in the hospital. I might not scrub necessarily for every case, depending on the seniority of training but I would be in the [hospital], or in the operating theatre, as an

absolute minimum. It just doesn't happen. I scrub for about 90%/95% of them." [HCP: BRI0023, Lower GI, RDE]

2.2. Pre-operative prevention

Pre-operative prevention such as smoking cessation and weight loss were strongly felt across both surgeons and stoma nurses to be important for PSH prevention.

a) Exercise as a PSH prevention strategy

Two of the stoma nurses felt that there may be a role for pre-operative exercise in PSH prevention. By strengthening the abdominal wall the nurses felt that this may help prevent a PSH. Some surgeons reported similar views, however, one surgeon disagreed and did not think pre-operative improvement of the abdominal wall strength would reduce PSH rates:

"Yes, we warn them about hernias; we tend to try and tell them about… If they are already fairly fit, we tell them about doing abdominal muscle strengthening exercises. Most of our patients are older and that would mean nothing to them, so there isn't really anything." [HCP: BRI0002, Stoma Nurse, BRI]

"Unless it's someone like someone who's having it done for your colitis or Crohn's – medical – and they know and you could say to them, "It might be advisable to try and build up a few muscles, you know. I can't see these older people coming into clinic, saying to them, "Go and do 20 sit-ups every day. It might help you." [HCP: BRI0003, Stoma Nurse, BRI]

"Well you can't do it in emergencies but preoperatively we can get patients to improve their core. That's particularly prudent for those that have had chemo and radiotherapy where we know they get a reduction in

their exercise tolerance and cardiopulmonary reserve and all the rest of it." [HCP: BRI0015, Surgeon, Lower GI, RDE]

"I don't think abdominal or exercises would help um hhhhh because they're… you're not uh hhhh I doubt doing a lot of sit, abdominal doing a lot of sit ups or something beforehand I doubt that would significantly help, it would be interesting." [HCP: BRI0036, Surgeon, Lower GI, BRI]

b) Smoking cessation and weight loss

Pre-operative smoking cessation and weight loss were both considered to be important to PSH prevention by both surgeons and stoma nurses. One surgeon suggested that pre-operative cessation of smoking and weight loss may have a bigger impact on PSH rates than any technical variation (BRI0004). However, by comparison BRI0023 was less convinced but still felt that pre-operative cessation of smoking and weight loss was "probably a good idea".

"I think the biggest gains to be had with this are what we can do in the elective setting, about how we optimise patients beforehand by controlling weight, and people not smoking, I think will probably ultimately have a far bigger impact than any technical thing that we can do." [HCP: BRI0004, Surgeon Lower GI, BRI]"

Interviewer: "I was wondering also about pre and postoperative factors, more like things that the stoma nurses can affect. We've spoken about smoking, [so obviously] stopping smoking, but more abdominal exercises, pre and post op. What do you think of those?"

Respondent: "Probably a good idea. Unlikely to cause the patient any harm. May cause benefit." [HCP: BRI0023, Lower GI, RDE]

"I think smoking cessation yes, addressing the risk factors, addressing obesity if I have time would yes, would help. Um wearing a support… well that's still pre operative, so yes smoking cessation, addressing the risk factor including obesity." [HCP: BRI0036, Surgeon, Lower GI, BRI]

"It starts way back when you see these people in clinic and you tell them to lose weight, to keep fit and to stop smoking, those things are hugely important." [HCP: BRI0022, Surgeon, Lower GI, RDE]

c) Antibiotics given intra or pre-operatively

Non-participant observations also identified the administration of antibiotics prior to the start of the surgery as another non-technical variation, though its significance was not discussed.

2.3. Post-operative factors

Post-operative factors such as complication of surgery were considered to be very important to PSH prevention. The post-operative factors identified included infection, ischemia, retraction, reoperation, post-operative sepsis or chest infection and raised intra-abdominal pressure post operatively were all considered to increase the risk of the patient developing a PSH. This was mostly felt to be due to poor wound healing. Other possible surrogates for post-operative complications that were identified included a post-operative admission to the Intensive Care or High Dependency Units.

"Respondent: as soon as you get a complication with a stoma and re-operate on it then I think you've got very high chance of parastomal hernia.

Interviewer: If you had a stoma infection or parastomal infection post operatively that could cause… you're predisposed to parastomal hernias?

Respondent: Yea, yea, yea I'm sure uh most of those would just be skin to be honest it's quite unusual to get a particularly deep parastomal infection." [HCP: BRI0036, Surgeon, Lower GI, BRI]

"If it's devascularise then you're gonna by, by definition have ischemic stoma. I And that will cause poor healing and that potentially might… Well you get a black stoma or at least you can get stenosis afterwards even if you don't have to take it back to refascia it. I Hmm S So you make the hole bigger to stop that happening and then you're gonna get a higher problems of parastomal hernias…You're trying to avoid you kinda making it ischemic which will be the worse thing because you may have to re-operate on them but in doing so you can end up with a higher chance of parastomal hernia and they're big patients they just got the pressure on." [HCP: BRI0036, Surgeon, Lower GI, BRI]

"I think if you get sepsis or retraction of your stoma it makes you worry that you've either made the gap too big, or you made it too tight, or you've not optimally formed the stoma. I can't really define that more, I don't think.

That might worry you, that you will be more likely to get problems, particularly if you had sepsis in the site of the stoma. You worry that the sepsis would injure the tissues, make them less able to retain the abdominal contents within, and then form a hernia later." [HCP: BRI0018, Surgeon, Hepatobillary, RDE]

"If patients smoke and they're going under an anaesthetic it's actually pretty dodgy ground cos you know the risk of aspirations really quite high

and if patients like smoke they're gonna cough a lot more as well thus hernia will pop up (laugh)" [HCP: BRI0035, Stoma Nurse, RDE]

Another post-operative factor discussed was whether or not the patient was put on the enhanced recovery pathway. The enhanced recovery pathway is a protocol for post-operative care that includes early mobilisation. The stoma nurses felt strongly that the patient being place on the enhanced recovery pathway would encourage PSH development. However, the surgeons generally disagreed and felt that the benefits on the enhanced recovery programme out-weighed the risk of developing a PSH.

"If patients are going to get a chest infection afterwards, and cough, and cough, and cough, or I've seen patients that sit straight up in bed when they're told on an enhanced recovery, "Come on, get out of bed," and they're not told, "Roll on your side, push yourself up. Be careful of your abdominal muscles…I don't know if parastomal hernias are more prevalent with enhanced recovery, but I wouldn't be surprised if that was found to be the case, because patients get up quickly, they get moving quickly, and they get discharged quite quickly. I'm not sure how much ward staff are teaching them about hernia prevention and abdominal care, so I think that's probably quite a big factor." [HCP: BRI0002, Stoma Nurse, BRI]

"I think it is, probably, with the enhanced recovery you have greater mobility and they get them up much quicker, but I'm not sure if they're actually taught the correct way of doing it. I think they use these muscles too much when they get up and they're damaging that before they've had a chance to heal up. They get up quite quickly. Often, if they have surgery in the morning, depending what surgery they've had and how quick it's been, they actually can be up that very evening. That's quite sudden really." [HCP: BRI0003, Stoma Nurse, BRI]

"One could hypothesise that early mobilisation might increase your risk, but personally I don't think early mobilisation would make any difference." [HCP: BRI0001, Surgeon, Upper GI, BRI]

"Interviewer: Early mobilisation, and early strain on the abdominal wall post-operatively. What do you think about that?

Respondent: I don't believe that. (Laughter)." [HCP: BRI0004, Surgeon Lower GI, BRI]

"There are so many other benefits to enhanced care I'm a little bit wary, I think, of necessarily labelling that as a problem." [HCP: BRI0018, Surgeon, Hepatobillary, RDE]

2.4. Post-operative prevention

A range of post-operative factors were thought by the participants to potentially influence development of PSH. These were mainly patient behaviour related. Examples of this included returning to exercise too quickly, heavy lifting, wearing a stoma belt for addition protection, early engagement with the core muscles, and receiving stoma nurse advice on coughing techniques to prevent the rise in intra-abdominal pressure causing a PSH. While some surgeons and all stoma nurses felt that some post-operative factors were important for PSH prevention, some surgeons (BRI0001) disagreed.

"Post-operatively, I don't think there's anything that you could do to make a difference, because I think the technical thing has happened and the patient is the patient." [HCP: BRI0001, Surgeon, Upper GI, BRI]

"Definitely and coughing post op is definitely an issue because sometimes a patient… when we see them the first couple of days post op sometimes you're see them like coughing and spluttering and really sort of like you know really having a good old cough and in those real early days that actually can make that abdominal wall more susceptible to a hernia, even at a real early stage post op um but and also with pain we also tell people… we make them little cough pillows so you put them on their stomach and tell them to engage their muscles before doing a cough that then helps with a. the pain and b. because they've engaged their abdominal muscles um they are less likely to develop a hernia so even at a real early stage that hernia prevention needs to be drummed into them..." [HCP: BRI0035, Stoma Nurse, RDE]

Stoma nurses particularly felt that wearing support garments would improve PSH rates. However, when asked about the role of support garments in PSH prevention two surgeons (BRI0032 and BRI0004) felt that support garments were unlikely to provide much benefit. While a third (BRI0022) felt that support garments "couldn't do much harm".

"A lot of patients say to me, "Can I go back to the gym?" "Can I go back to cycling?" "Can I go back to swimming?" "What stroke should I do in swimming that's less likely to cause a hernia?" I don't know. I tend to tell them to do a gentle breaststroke. Front crawl seems to me to be a strain, but then if you think about breaststroke, [just it's fibre 0:07:48], isn't it? So, I just tell them to be careful…Certainly a lot of my female patients say, "Can I go back to yoga and Pilates?" I say, "Yes, but again wear support garments and tell the instructor that you've got a stoma." There are abdominal muscle exercises and there's a little leaflet we have out there, but there's only about three exercises in total." [HCP: BRI0002, Stoma Nurse, BRI]

"I don't know; it can be they could have just lifted up something and then they suddenly notice a bit of swelling and bulging and I'm like, "Yes, that's why you shouldn't really do any heavy lifting, really, unless you've got a support belt on… When I talk to patients when they come back to me, I tell them they're not to do any heavy lifting, and I say, "Three months" – a good three months. They go, "Look at me," and I go, "No, I mean it: a good three months. You need that much time for it to heal. Actually, if you can avoid any heavy lifting, avoid it." [HCP: BRI0003, Stoma Nurse, BRI]

"Support garments and exercise afterwards, I don't see how they can do any harm. I don't think we have any high quality evidence to say that they help, but again all of these things logically make sense that they will improve it and maybe keep your abdominal core strength stronger you think they would help." [HCP: BRI0022, Surgeon, Lower GI, RDE]

"I can't see why stoma support belts would make any difference in terms of prophylaxis or exercise, nutrition probably should, as it would do with all complications." [HCP: BRI0032, Surgeon Lower GI, RDE]

"In terms of preventing it? I don't think wearing a support or a corset immediately after the operation is going to reduce the risk of parastomal hernia formation, at all. I don't think there is anything that the stoma nurses can do to prevent a hernia forming." [HCP: BRI0004, Surgeon Lower GI, BRI]"

The stoma nurses and one surgeon (BRI0015) also felt that post-operative abdominal exercise may improve PSH rates.

"Yea and they're really good exercises (the core four) um to you know reduce the incidences of hernia and then sort of 4 to 6 weeks down the line they can then start reintroducing their usual exercises." [HCP: BRI0035, Stoma Nurse, RDE]

"Well you can watch my core four video, which is to improve people's core, their four core muscles post-surgery as part of stoma education. I also send people to pilates, tai chi, and yoga classes because your abdominal core is important. It's not just about your abdominal wall, it's about your obliques, it's also about erector spinae, your posture and all the rest of it." [HCP: BRI0015, Surgeon, Lower GI, RDE]

Appendix 7 Long-list of data items with accompanying decision from consensus meeting.

Discussion 1: technical variations			Essential	Desirable	Not required	Notes
1. Surgical approach to stoma formation						
a. Context of stoma formation	Stoma formed in isolation			1		Add indication and name of procedure
	Stoma formed as part of another procedure			1		
b. Type of access used	Laparoscopic		1			
	Open		1			
	Trephine		1			
c. Type of stoma formed	End	Primary	1			
		Secondary (conversion of loop to end)	1			
	Loop	Single barreled (with and without rod)	1			
		Double barreled	1			
	Loop end (Abcarian)		1			
	Other		1			
d. Envisaged longevity of stoma	Temporary		1			
	Permanent		1			

Discussion 1: technical variations			Essential	Desirable	Not required	Notes
	Uncertain		1			
e. Section of bowel used to form the functioning end of the stoma	Ileum		1			Add response category Jejunum
	Sigmoid colon		1			
	Transverse colon		1			
	Ascending colon		1			
	Other			1		
f. Bowel mobilisation	None	Stoma not under tension			1	
		Stoma under tension			1	
	To splenic flexure				1	
	To hepatic flexure				1	
	Other				1	
g. Stoma site	Pre-marked Y/N	Stoma formed at pre-marked site [preserved with suture, pen or not preserved]	1			Add in who marked the site: Stoma nurse, Surgeon, specialist nurses, other
		Stoma not formed at pre-marked site	1			
h. Route of stoma	Trans-peritoneal		1			
	Extra-peritoneal		1			
	Oblique				1	

Discussion 1: technical variations			Essential	Desirable	Not required	Notes
2. Trephine formation: skin and subcutaneous tissue						
a. Skin incision	Method of creating incision	Scalpel			1	
		Diathermy			1	
	Shape of incision	Circular			1	
		Cruciate			1	
		Oval			1	
		Other			1	
	Measurement of incision size	Finger breadths			1	
		Ruler			1	
		Eye			1	
		Other			1	
	Size of incision [widest diameter in cm]				1	
	Adjustments made to incision	Blunt [retractor, manually]			1	
		Sharp [scalpel, diathermy, scissors]			1	
	Location of incision	Through an incision from the same operation [port site, midline, paramedian, umbilicus, other]		1		
		Through an incision from a previous operation [*port site, midline, paramedian, umbilicus, other*]		1		
		Through a separate incision		1		

Discussion 1: technical variations			Essential	Desirable	Not required	Notes
b. Subcutaneous tissue	Tissue divided but not excised		1			Subcutaneous tissue excised Y/N
	Tissue excised	Shape of excised tissue [*cone, core, other*]			1	
3. Trephine formation: muscle layers						
a. Relationship to rectus abdominis	Within the belly of rectus		1			
	Outside the belly of rectus	Within rectus sheath	1			
		Within oblique abdominal muscles	1			
	Other				1	
b. Relationship to arcuate line	Above				1	
	Below				1	
c. Relationship to linea semilunaris	Disrupts				1	
	Does not disrupt				1	
	Uncertain				1	
d. Anterior sheath	No incision made	Blunt puncture [trocar, scissors, mechanical device, other]	1			Amend to laparoscopic Trocar used Y/N
		Other			1	
	Incision made	Size of incision [widest diameter in cm]	1			

Discussion 1: technical variations			Essential	Desirable	Not required	Notes
		Shape of incision [linear (horizontal, vertical, cruciate, circular, other]	1			Add was any fascia removed
		Use of sutures to close the margins?		1		
		Measurement of incision size [finger breadths, ruler, by eye, other]			1	
	Adjustments made to incision/ puncture	Blunt [retractor, manually, scissors, other]	1			Y/N only to adjustments made
		Sharp [scalpel, diathermy, other]			1	
e. Posterior sheath	No incision made	Layer punctured bluntly [trocar, scissors, mechanical device, other]	1			Amend to laparoscopic Trocar used Y/N
		Other			1	
	Incision made	Size of incision [widest diameter in cm]	1			
		Shape of incision [linear (horizontal, vertical), cruciate, circular, other]	1			Add was any fascia removed
		Measurement of incision size [finger breadths, ruler, by eye, other]			1	
	Use of sutures to close the margins			1		
	Adjustments made to incision/ puncture	Blunt [retractor, manually, scissors]	1			Y/N only to adjustments made
		Sharp [scalpel, diathermy]			1	

Discussion 1: technical variations				Essential	Desirable	Not required	Notes
f. Muscle fibres	Separated	Blunt [trocar, scissors, mechanical device, other]		1			Y/N to separated only
		Sharp [scalpel, diathermy]				1	
	Not separated	Retracted sideways (e.g. LRAPS technique)		1			Include as part of 2a)
		Other				1	
4. Trephine formation: other							
a. Intra-operative nerve damage	Epigastric nerve					1	
	Lower thoracic nerve					1	
	Other					1	
b. Intra-operative vessel damage	Epigastric vessel				1		
	Other				1		
b. Laparoscopic procedures	Location of trephine in relation to port site	Trephine created at port site	Trephine created at beginning of procedure [*then subsequently used as port site*]	1			
			Trephine created at end of procedure* [*conversion of port site to trephine*]	1			
		Trephine not created at port site		1			
		Same intra-abdominal pressure maintained			1		

Discussion 1: technical variations			Essential	Desirable	Not required	Notes
	Abdomen inflated during trephine formation	Intra-abdominal pressure reduced		1		
	Abdomen deflated during trephine formation			1		
	Abdomen re-inflated following trephine formation				1	
5. Reinforcing the stoma trephine with mesh (part 1)						
a. Mesh type	Synthetic	Non-absorbable [polypropylene, polyethylene terephthalate, polytetrafluoroethylen (PTFE), polyvinylidene fluoride (PVDF), other]	1			Y/N for mesh use. Ask for mesh product code only
		Absorbable [rapid, delayed]			1	
		Combined			1	
	Biologic				1	
	Other				1	
b. Mesh size	Size of mesh inserted [height and width measured in cm OR if circular widest	Mesh was uncut/unadjusted	1			Phrasing change to whether shape was changed from original
		Mesh not cut/adjusted	1			

Discussion 1: technical variations			Essential	Desirable	Not required	Notes
	diameter in cm]					
	Mesh size estimation	Finger breadths			1	
		Ruler			1	
		Eye			1	
		Other			1	
c. Shape of inserted mesh	2D	Oval			1	
		Square			1	
		Circle			1	
		Other			1	
	3D	Funnel			1	
		Other			1	
d. d. Location of mesh and mechanism of creating space	Sublay [pre-peritoneal, retro-rectus]	Space created by instrumental dissection	1			Use a diagram to indicate location
		Space created with blunt force (e.g. finger)			1	
		Combination			1	
		Other			1	
	Onlay [supra-rectus]	Space created by instrumental dissection			1	
		Space created with blunt force (e.g. finger)			1	
		Combination			1	

Discussion 1: technical variations				Essential	Desirable	Not required	Notes
		Other				1	
	Inlay [intra-rectus]					1	
	Underlay [intra-peritoneal, IPOM]					1	
e. Route used to position mesh	Through the main operative incision			1			
	Through the stoma trephine			1			
	Via a port			1			
	Other			1			
6. Reinforcing the stoma trephine with mesh (part 2)							
a. Mesh trephine	Sugarbaker (mesh edges secured to fascial edges)				1		
	Modified Sugarbaker (mesh edges secured overlapping the fascial edges)			1			
	Key-hole (trephine within the mesh) Y/N	Size of key-hole (widest diameter in cm)		1			Should get from product code. Change to if adjusted what was size and shape changed to
		Shape of key-hole	Circular			1	
			Cruciate			1	
			Other			1	
		Key-hole created using a mechanical device (other than the tacker)				1	

Discussion 1: technical variations				Essential	Desirable	Not required	Notes
		Key-hole created before mesh has been secured				1	
		Key-hole created after mesh has been secured				1	
b. Securing the mesh	Not secured					1	
	Securing the mesh to the abdominal wall	Tacking	Single crown	1			Y/N to secured to abdominal wall only
			Double crown			1	
			Other			1	
		Suturing	Continuous			1	
			Interrupted [entire perimeter, corners only, other]			1	
		Suture choice	Absorbable			1	
			Non-absorbable			1	
		Glue				1	
		Combination of tacks and sutures				1	
		Mechanical device to secure the mesh (other than tacker)				1	
		Other				1	
	Securing the mesh to the stoma serosa	Suturing	Interrupted [number and position]	1			
			Continuous			1	
			Other			1	
			Absorbable			1	

Discussion 1: technical variations				Essential	Desirable	Not required	Notes
		Suture choice	Non-absorbable			1	
		Other				1	
7. Closure of the lateral space							
a. Fixation of the mesentery to the abdominal wall	Anatomical layer	Rectus sheath				1	
		Rectus muscle				1	
		Oblique muscle				1	
		Peritoneum				1	
	Method of fixation	Sutures	Continuous			1	
			Interrupted			1	
		Other				1	
b. Fixation of the stoma to the abdominal wall	Anatomical layer	Subcutaneous				1	
		Rectus sheath			1		Fixing to sheath Y/N
		Rectus muscle				1	
		Oblique				1	
		Peritoneum				1	
	Method of fixation	Sutures	Continuous			1	
			Interrupted			1	
			Purse string			1	

Discussion 1: technical variations				Essential	Desirable	Not required	Notes
			Other			1	
		Other				1	
8. Use of the stoma as a specimen extraction site							
a. Type of specimen	Large bowel			1			Y/N to stoma used as an extraction site only
	Small bowel					1	
b. Adjustments to trephine size	Trephine widened	Incision [scalpel, diathermy]				1	
		Blunt [manually, scissors, retractor, wound protector]				1	
	Closure of widened trephine					1	
9. Stoma snugness							
a. Mesentery stripping	Trimming of epiploic fat					1	
	Trimming of stoma mesentery					1	
b. Assessment of stoma snugness	Stoma digitation					1	
	Other					1	
10. Closure of other wounds formed during the procedure							
a. Timing of wound closure	Wounds closed prior to creation of stoma lumen					1	
	Wounds closed after creation of stoma lumen					1	
	Dressings applied prior to creation of stoma lumen					1	

Discussion 1: technical variations					Essential	Desirable	Not required	Notes
	Dressings applied after creation of stoma lumen						1	
	Abdomen cleaned prior to creation of stoma lumen						1	
	Abdomen cleaned after creation of stoma lumen						1	
b. Layers of closure	Deep layers	Main incision	Sutured closed	Small bite closure	1			
				Large bite closure	1			
			Not sutured closed		1			
		10mm port	Sutured closed	Small bite	1			Amend to deep layer closure of biggest port site Y/N
				Large bite			1	
			Not sutured closed		1			
		5mm port	Sutured closed	Small bite			1	
				Large bite			1	
			Not sutured closed				1	
	Skin layer		Closed with sutures	Interrupted			1	
				Continuous			1	
			Closed with staples				1	
			Closed with glue				1	

Discussion 1: technical variations				Essential	Desirable	Not required	Notes
11. Creating and securing the stoma lumen							
a. Reducing faecal spillage	Stoma lumen clamped					1	
	Stoma lumen stapled					1	
	Stoma lumen sutured					1	
b. Cleaning of stoma lumen	Anti-septic	Betadine				1	
		Other				1	
	Other					1	
c. Suturing of bowel to skin	Spouted	3 point sutures		1			Stoma spouted Y/N
		Other				1	
	Not spouted					1	
	Skin bite	Full thickness				1	
		Subcuticular				1	
	Method of suturing	Interrupted				1	
		Purse string				1	
	Muco-cutaneous junction	Gaps present	Protruding subcutaneous fat			1	
			No protruding subcutaneous fat			1	
		No gaps present				1	
Total				**56**	**15**	**136**	

Discussion 2: non-technical variations			Essential	Desirable	Not required	Notes
1. Patient factors						
a. Gender			1			
b. Age	DOB		1			
c. Co-morbidities	Respiratory disorder(s)			1		
	Cardiac disorder(s)				1	
	Immunosuppressive disorder(s)				1	
	Metabolic disorder(s)	Diabetes [*Type 1, 2*]	1			
		Other			1	
	Renal dysfunction/failure		1			CKD
	Cardiac disorder(s)				1	
	Jaundice				1	
	Other				1	
d. ASA grade			1			
e. Smoking status	Non-smoker		1			
	Ex-smoker		1			
	Current smoker		1			

Discussion 2: non-technical variations		Essential	Desirable	Not required	Notes
f. Obesity	Body mass index	1			Change to height and weight
	Waist circumference			1	
	Subcutaneous fat thickness			1	
g. Raised intra-abdominal pressure	Extra-abdominal cause [*chronic cough, other*]			1	
	Intra-abdominal cause [chronic constipation, ascites, obstructive uropathy, prostatic hypertrophy, other]			1	l
h. Malignancy	Current [received chemo/radiotherapy]	1			Received chemotherapy in last 12 m
	Previous [received chemo/radiotherapy]	1			Received abdomino / pelvic radiotherapy last 12m
	Inflammatory bowel disease [*Crohns, ulcerative colitis*]			1	

Discussion 2: non-technical variations		Essential	Desirable	Not required	Notes
i. Existing bowel conditions	Diverticular disease			1	
j. Malnutrition		1			Change to overall frailty score
k. Medication	Corticosteroids	1			Therapeutic oral or injected corticosteroids in last 12m
	Disease modifying agents	1			DMARDs and other (immunosuppressive drugs) within past 6 weeks
	Anti-coagulants	1			Add 'other' immunosuppressive
	Previous surgery [at site of planned stoma, at other site]	1			

Discussion 2: non-technical variations					Essential	Desirable	Not required	Notes
1. Conditions weakening the abdominal wall	Abdominal wall hernia [*previous, existing*]				1			
	Pregnancy [current, previous]					1		
	Connective tissue disorder (Including aneurysm disease)				1			
2. Operation-specific factors								
a. Urgency of operation	Elective				1			
	Scheduled				1			
	Emergency						1	
	Immediate						1	
c. Timing of procedure	Day						1	
	Evening						1	
	Night						1	
d. Context of stoma formation	In isolation	Grade of surgeon	Trainee	Supervised by a consultant [*scrubbed, unscrubbed*]	1			GMC number and grade of most senior surgeon
				Supervised by another trainee [*scrubbed, unscrubbed*]			1	
				Unsupervised			1	

Discussion 2: non-technical variations					Essential	Desirable	Not required	Notes
			Consultant [single/dual operating]				1	
	Part of another procedure	Grade of surgeon (procedure)	Trainee	Supervised by a consultant [*scrubbed, unscrubbed*]			1	
				Supervised by another trainee [*scrubbed, unscrubbed*]			1	
				Unsupervised			1	
			Consultant [single/dual operating]				1	
		Grade of surgeon (stoma)	Trainee	Supervised by a consultant [*scrubbed, unscrubbed*]			1	
				Supervised by another trainee [*scrubbed, unscrubbed*]			1	
				Unsupervised			1	
			Consultant [single/dual operating]				1	

Discussion 2: non-technical variations			Essential	Desirable	Not required	Notes
e. Type of surgeon performing procedure	Colorectal		1			What specialty was most senior person in the room
	Upper GI				1	
	Emergency				1	
	Other				1	
f. Intra-operative factors	Peri-operative antibiotics				1	
	Blood loss				1	
	Contamination [faeces, pus, fluid, other]				1	
	Evidence of obstruction	Complete	1			Y/N to evidence of obstruction only
		Partial			1	
	Evidence of dilated bowel	At stoma site			1	
		Elsewhere			1	
	Evidence of oedematous bowel	At stoma site			1	
		Elsewhere			1	
3. Pre- and post-operative factors						

Discussion 2: non-technical variations				Essential	Desirable	Not required	Notes
a. Pre-operative preparation	Bowel preparation administered					1	
	Consultation with stoma nurse			1			Combine with stoma marked in discussion 1
	Modification of co-morbidities	Smoking cessation				1	
		Weight loss				1	
		Cessation of medications				1	
		Exercise programme				1	
		Optimisation of diabetic control				1	
		Other				1	
b. Post-operative care	Enhanced recovery pathway			1			Change to day mobilised - defined as patient walking
	Admission to HDU/ITU		Planned	1			
			Unplanned	1			

Discussion 2: non-technical variations					Essential	Desirable	Not required	Notes
c. Complications	Wound complication	Infection	Stoma site		1			
			Other site		1			Change 'other site' to 'main incision'
		Seroma	Stoma site		1			Add haematoma as a complication
			Other site		1			Change 'other site' to 'main incision'
	Respiratory complication						1	
	Complication leading to raised intra-abdominal pressure						1	
	Stoma-related complication	Abscess			1			Add mucocutanious dehiscence
		Retraction			1			
		Stenosis			1			
		Prolapse			1			
		Ischaemia			1			

Discussion 2: non-technical variations			Essential	Desirable	Not required	Notes
		Necrosis	1			
	Complication requiring re-operation		1			Within Clavian-Dindo classification
d. Post-operative advice	Abstinence from heavy lifting		1			Have you abstained from heavy lifting
	Use of support garment		1			Have you Y/N at 30 day Follow-up
	Introduction of abdominal wall strengthening exercises		1			Have you Y/N at 30 day Follow-up
			Total = 41	Total = 2	Total = 48	

Appendix 8: Short-list of data items for inclusion in the CIPHER case report forms.

1. Surgical approach to stoma formation			Essential	Desirable
a. Context of stoma formation	Indication for surgery			
	Name of procedure			
b. Intended type of access used	Minimally invasive [SILS; Laparoscopic; Robotic]		1	
	Open		1	
	Trephine		1	
c. Intended type of procedure converted to open	Conversion from minimally invasive to open [SIL converted, Laparoscopic converted; Robotic converted] Y/N			
c. Type of stoma formed	Envisaged longevity of stoma [permanent, uncertain]		1	
	End		1	
	Loop	With or without rod	1	
	Loop end (Abcarian)		1	
	Double barreled		1	
d. Section of bowel used to form functioning end of stoma	Jejunum		1	
	Ileum		1	
	Ascending colon		1	
	Transverse colon		1	
	Descending colon			
	Sigmoid colon		1	
e. Stoma site		Stoma site marked by [stoma nurse, surgeon, non-specialist nurse, other]	1	

1. Surgical approach to stoma formation			Essential	Desirable
	Stoma site pre-marked Y/N [preserved with suture, pen or not preserved]	Stoma formed/ not formed at pre-marked site (Y/N)	1	
f. Route of stoma	Trans-peritoneal		1	
	Extra-peritoneal (cannot be trephine in section b)		1	

2. Trephine formation				
b. Subcutaneous tissue	Subcutaneous tissue excised (Y/N)		1	
c. Relationship of the muscle layer incision to the rectus abdominis	Outside of the rectus sheath (Within oblique abdominal muscles)		1	
	Within the rectus sheath	Through the belly of the rectus abdominis	1	
		Lateral to the belly of the rectus abdominis* (e.g. LRAPS technique)	1	
d. Anterior sheath (ONLY if within the rectus sheath*)	Was a laparoscopic trocar used to puncture the anterior sheath (Y/N) (only for minimally invasive Laparoscopic + robotic OR converted Laparoscopic + robotic procedure) NOT SILS or SILS converted		1	
	Size of incision [widest diameter in mm]		1	
	Shape of incision [linear (horizontal, vertical), cruciate, circular, other]		1	
	Was any of the anterior sheath removed? (Y/N)		1	
	Adjustments made to the size of the incision (Y/N)	Sutures used to buttress end of incision (Y/N)	1	
e. Posterior sheath (ONLY within the rectus sheath*)	Was a laparoscopic trocar used to puncture the anterior sheath (Y/N) (only for minimally invasive Laparoscopic + robotic OR converted Laparoscopic + robotic procedure) NOT SILS or SILS converted		1	
	Size of incision [widest diameter in mm]		1	
	Shape of incision [linear (horizontal, vertical), cruciate, circular, other]		1	
	Was any of the posterior sheath removed? (Y/N)		1	
	Adjustments made to the size of the incision (Y/N)	Sutures used to buttress end of incision (Y/N)	1	
f. Muscle fibres	Separated with blunt dissection (Y/N) Only possible if within rectus belly/oblique muscles		1	
g. Intra-operative vessel damage	Epigastric vessel (Y/N)			1
h. Laparoscopic procedures	Location of trephine in	Trephine created at the port site at the beginning of procedure [then subsequently used as port site]	1	

(only for minimally invasive Laparoscopic + robotic OR converted Laparoscopic + robotic procedure) NOT SILS	relation to port site	Trephine created at port site	Trephine created at end of procedure [conversion of port site to trephine]	1	
		Trephine created in a location other than port site		1	

3. Reinforcing the stoma trephine with mesh				
a. Mesh type	Mesh used (Y/N)	Product code, fix label, provide manufacture name	1	
b. Mesh size	Mesh cut or adjusted (Y/N)	Size of mesh inserted if changed from original (Y/N) [height and width measured in cm OR if circular/oval diameter in cm	1	
			1	
		Shape of mesh if changed from original (Y/N) [3D/funnel; Circular/oval; Square/rectangular]	1	
c. Location of mesh placement	Please indicate using diagram [Diagram provided with the following drop-down categories: Sublay/pre-peritoneal/retro-rectus; Underlay/intra-peritoneal; Onlay; Inlay]		1	
d. Route used to position mesh	Through the main operative incision (e.g. in an open procedure or an extended port site) (any type of surgery) (can be all three: onlay, intraperitoneal or retorectus)		1	
	Through the stoma trephine (any type of surgery) (can be all three: onlay, intraperitoneal or retorectus)		1	
	Via a port (Any minimally invasive or converted procedure) (can only be intraperitoneal placement of mesh)		1	

e. Mesh trephine	Modified Sugarbaker (mesh edges secured overlapping the fascial edges)		1	
	Keyhole Y/N	What shape was the keyhole [cruciate; circular/oval; Slit]	1	
		What was the size of the keyhole (Maximum diameter)	1	
f. Securing the mesh	Mesh secured to abdominal wall (including sheath, muscle, peritoneum) (Y/N)		1	
	Mesh secured to stoma serosa (Y/N)		1	

5. Use of the stoma as **a** specimen extraction site			
a. Stoma trephine used as a specimen extraction site	Stoma trephine used as an extraction site (Y/N)	1	

6. Closure of other wounds formed during the procedure				
a. **Closure of deep layers of the abdominal wall**	Main abdominal incision (e.g. in an open procedure, extended port site or specimen extraction site)	Small bite closure	1	
		Large bite closure	1	
		N/A		
	Biggest port site (e.g. 10, 11 or 12mm) (Minimally invasive laparoscopic + robotic OR converted laparoscopic + robotic procedures only)	Closure of deep layer Y/N	1	
			1	

7. Spouting the stoma lumen			
a. Suturing of bowel to skin	Has the stoma been spouted (Y/N)	1	

Non-technical variations			Essential	Desirabl e
1. Patient factors				
a. Sex			1	
b. Age	DOB		1	
c. Co-morbidities	Diabetes (on active medical treatment e.g. Insulin or oral tablets)		1	
	Renal dysfunction/failure (pre-existing renal condition)	CKD stage	1	
d. ASA grade			1	
e. Smoking status	Non-smoker – Never smoked		1	
	Ex-smoker – Minimum 3 months tobacco free		1	
	Current smoker		1	
f. Obesity	Height (cm)		1	
	Weight (Kg)			
g. Malignancy	Received chemotherapy in last 12 months (Y/N)		1	
	Received abdominal pelvic radiotherapy in last 12 months (Y/N)		1	
h. Medication	Therapeutic oral or injected corticosteroids (e.g. prednisolone, cortisone, dexamethasone, other)		1	
	Disease modifying agents (e.g. Methotrexate, Sulfasalazine, Hydroxychloroquine, Azathioprine, other) or biological agents (e.g. Etanercept, Adalimumab, Infliximab, other)		1	
	Other immunosuppressive medications (e.g. renal and transplant-related, such as Cyclosporin)			
i. Conditions weakening the abdominal wall	Previous abdominal surgery [at site of planned stoma, at other site] (Y/N)		1	
	Abdominal wall hernia [*previous, existing*] (Y/N)		1	
	Parity (number of pregnancies (>20 weeks)			1

	Connective tissue disorder (Including aneurysm disease, Ehlers-Danlos Syndrome, Marfan syndrome, Osteogenesis imperfecta, scleroderma, rheumatoid, SLE etc.)	1	
J. Frailty score		1	
a. Pre-operative stoma nurse consultation	Consultation with stoma nurse (Y/N)	1	

2. Operation-specific factors					
a. Urgency of operation	Elective (surgical procedure planned or booked in advance of routine admission to hospital)			1	
	Expedited (stable patient requiring early intervention for a condition that is not an immediate threat to life, limb or organ survival)			1	
b. Most senior surgeon scrubbed at the time of stoma formation	GMC number	Consultant	Colorectal (ACPGBI member)	1	
			Non-colorectal (not a member of ACPGBI)	1	
		Registrar	Colorectal trainee		
			Non-colorectal trainee		
		Senior house officer			
c. Intra-operative factors	Evidence of obstruction (Y/N)			1	

3. Post-operative factors collected prior to discharge					
a. Post-operative care	Day post op that the patient was mobilised (Day 0 = day of operation)			1	
	Admission to HDU/ITU (Y/N)	Planned		1	
		Unplanned		1	
b. Complications	Wound complication	Infection	Stoma site	1	
			Other incision site	1	
		Seroma	Stoma site	1	
			Other incision site	1	
		Haematoma	Stoma site	1	
			Other incision site	1	
	Stoma-related complication	Abscess		1	
		Retraction		1	
		Stenosis		1	
		Prolapse		1	
		Ischaemia		1	
		Necrosis		1	
		Muco-cutaneous dehiscence		1	
	Complications within Clavien-dindo classification of surgical complications			1	

4. Post-operative factors collected after discharge					
b. Complications	Wound complication	Infection	Stoma site	1	
			Other incision site		
	Stoma-related complication	Abscess		1	
		Retraction		1	
		Stenosis		1	
		Prolapse		1	
		Ischemia		1	
		Necrosis		1	
		Muco-cutaneous dehiscence		1	
	Complications within CCS classification or Clavien-dindo classification of surgical complications			1	
c. Post-operative advice at 30 day follow up	Have you abstained from heavy lifting (Y/N)			1	
	Have you used a support garment (Y/N)			1	
	Have you been performing abdominal wall strengthening exercises (Y/N)			1	